Bangladesh Investment Development Authority
BIDA

JICA

MEDICAL EQUIPMENT & DEVICES INDUSTRY IN BANGLADESH

Bangladesh Investment Development Authority
Prime Minister's Office
Government of the People's Republic of Bangladesh

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Executive Chairman
Bangladesh Investment
Development Authority (BIDA)
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Foreward

Bangladesh has been among the fastest growing economies in the world during the last decade, propelled by a demographic dividend, robust ready-made garment (RMG) industry, growing remittances, and stable macroeconomic conditions. The Bangladesh economy has maintained economic growth of over 6.5% on an average during the last decade. In spite of Covid19 pandemic, the Bangladesh economy grew at 3.75% and 6.94%in the FY 2019-20 and FY 2020-21 respectively and is forecasted to grow by 6.9 % in FY 2021-22 and 7.1% in FY 2022-23 (ADB), recovering gradually from the pandemic.

Over the years, the Bangladesh Investment Development Authority (BIDA) has been working relentlessly to facilitate private investments and diversification of industries in the country. Although the Bangladesh economy depends heavily on the RMG sector, there are several other industries with tremendous growth potential. Medical equipment and devices industry is among those industries with great future prospects. The significance of the healthcare and medical equipment and device industry was evident during the Covid19 pandemic and the urgent need to develop the sector remained most potently in the minds of the policymakers.

During this unprecedented challenging time, BIDA took the initiative to conduct a study of this relatively unexplored but very important sector with the support of the JICA Project team. The purpose of the study was to assess the current situation prevailing in the industry and find out the growth potential of the major segments of medical equipment & device industry. Stakeholders across the academia, government and private healthcare and medical equipment industry were consulted and interviewed. The findings have revealed the future growth potential of the industry as well as the challenges faced by the investors. Based on the findings, a number of recommendations have been placed. On March 2022, a National Seminar was held at BIDA to share the findings as well as to provide a platform for the stakeholders from the academia, industry and the government to share and exchange their opinions. Many of these stakeholder suggestions were also incorporated in the final recommendations.

BIDA has taken the responsibility to take proactive measures to facilitate the implementation of these recommendations. I believe that once the recommendations are implemented, it will not only help the current industry players but also raise the level of indigenous manufacturing by attracting increasing private investments into the sector in the near future. We hope that this report will form the basis for continued discussion and appropriate action to support the growth of the medical devices industry in Bangladesh.

Md. Sirazul Islam

Acknowledgement

The study has been conducted under the guidance of Ms. Mohsina Yasmin, Executive Member, Foreign Investment Promotion, Bangladesh Investment Development Authority. The report was authored by Mr. Taro Tsubogo, Team Leader, JICA Project Team, Ms Sharmin Hossain, JICA National Consultant, Mr. Fariaz Ahmed, JICA National Consultant and Mr. Takashi Shimada, JICA Consultant.

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Executive Summary

An important social and economic contributor to the country, the Bangladesh healthcare industry has been growing at a healthy rate and has developed significantly during the last decade. While the pharmaceutical industry has grown from strength to strength with 98 percent of the domestic demand for drugs being produced in the country currently, the healthcare service delivery and the medical devices & equipment industry, in particular, is still at a nascent stage with 92 percent of medical devices and equipment being imported. Although the medical devices sector plays a critical role in improving healthcare access, the prevailing ecosystem needs special intervention to drive the manufacturing of medical devices in Bangladesh and a number of challenges need to be addressed in providing access to quality, and affordable healthcare in the country.

BIDA together with the JICA Project team undertook this study to find out the present status of the industry, and the prospects of manufacturing medical devices in Bangladesh, to identify the segments that can be promoted for local production as well as to uncover the challenges hindering the growth of manufacturing in the country and to formulate a roadmap for the development of the industry.

A combination of both primary and secondary research was conducted to understand the current situation prevailing in the industry. Stakeholders across the academia, industry, and government were interviewed and regulators were consulted for their views and opinions. A total of 15 medical device manufacturers and importers were interviewed. In addition, to assess the demand for medical equipment, several hospitals, clinics, and diagnostics were interviewed.

The total healthcare expenditure in Bangladesh was only 2.48% of GDP in 2019, with the government allocation being less than 1% of GDP. The budget allocation towards the healthcare sector has been hovering around 5% for the last several years. In 2019, the out-of-pocket expenditure was as high as 73%, with the insurance penetration ratio being only 0.5% only whereas the average in the emerging countries was 3.3%. The per capita spending stood at USD 46 in 2019, which is low compared to regional peers. While the per capita income is lower than regional peers, it has been growing at a healthy rate of around 10% for the last five years. Between 2000 and 2019, health expenditure per capita in Bangladesh grew substantially from USD 9 to 46 US dollars. The import of Bangladesh medical devices has been growing at a CAGR of around 10%, significantly higher than the global industry growth of 4-6%. The market was estimated to be over USD 500 million in June 20021.

The medical equipment and device industry are dependent on imports with only products in the lower end of the technology value chain being produced in the country. The import is dominated by diagnostic equipment and instruments and appliance accounting for 50 percent of the total import (in terms of value). The Bangladesh medical devices industry comprises several segments – consumables and implants,

diagnostic imaging, instruments & appliances, patient aids, and In-Vitro devices. The size of indigenous manufacturing is small and is characterized by the presence of both domestic and joint ventures with MNC. At present, indigenous manufacturing is limited to the consumables segment followed by orthopedic supplies, medical furniture, and basic electro-diagnostic equipment. These items are categorized mainly as class-A and -B in the medical device classification of the Registration Guidelines.

The study found that there is a great potential for expanding the manufacturing of medical devices and equipment in Bangladesh. Demand-side dynamics provide an unprecedented opportunity for manufacturing of medical devices in Bangladesh with the market size expected to cross USD 800 million by 2025 supported by increasing income and affordability among the population which is expected to lead to higher demand and utilization of healthcare services. In addition, rising awareness among the population and the significance of early detection towards prevention of disease, and the increasing prevalence of chronic diseases requiring long term treatment plans is expected to further drive the demand for healthcare services. Moreover, the overall growth in healthcare infrastructure driven by the government plans for expansion of healthcare delivery channels is expected to increase the per capita consumption of medical devices and equipment.

Capitalizing on these factors, Bangladesh can focus on manufacturing low and mid-tech products mainly ranging from the Class-A to -B (according to DGDA guidelines) in the short- to mid-term with a gradual shift towards developing the capacity for designing and manufacturing high-tech products in the longer term. The study found that the demand for cardiovascular devices, IVD devices/kits, diagnostic imaging equipment and devices, consumables, and OT/ICU equipment was forecasted to have higher growth in the near future. Interviews with current and prospective investors have revealed that they were considering consumables, hospital furniture, some items of IVD kits/ reagents, OT/ ICU equipment, and some disease-specific devices)/products to have the highest potential for indigenous manufacturing.

However, the study found the presence of many challenges which were hindering the growth of the sector in Bangladesh which needed to be addressed to realize the growth potential. Several factors relating to the policy framework and tax structure lead to high dependence on imports. These include unfavorable import duty structure which makes the import of finished goods cheaper compared to the import of raw materials limiting any scope for value addition in many segments, complex and bureaucratic regulation & rules, lack of backward linkage support industry, and limited access to funding.

To develop the sector, there is an immediate need for the Government, Industry (Medical devices players, healthcare providers) and other stakeholders (academia, research institutes and funding agencies) to collaborate and make coordinated and concerted efforts to promote manufacturing of medical equipment and devices in Bangladesh. Accordingly, the relevant stakeholders of Bangladesh are advised to consider and implement policy measures and actions, covering i) attraction of investment by the foreign potential manufacturers, ii) facilitation of reinvestments by existing investors, iii) development of skills/ technology, iv) easing of regulatory and operational environment specific to the sector, and v) others, for each of short-

to mid-term and mid- to long-term perspectives. The detailed Roadmap and policy recommendations are provided in Chapter 4.

To promote the manufacturing of medical equipment/ devices in the short- to mid-term, it is essential to proactively attract both foreign and local investments to this sector and also pay attention to the existing investors in the sector to facilitate reinvestments plans(expanding or diversification of existing businesses) of current investors/manufacturers, while also making an effort to develop skills/ technology of local human resources for product development and manufacturing, ideally through partnership or collaboration with foreign manufacturers. At the same time, it is important to ease the regulatory and operational environment specific to this sector to ensure a predictable and smooth establishment of investments, in particular. Additionally, the role of industry associations, funding institutions, and agencies including banks, PE/VC, incubators, etc. is critical in supporting the development of the manufacturing ecosystem. Moreover, a collaboration between academia and industry is essential in developing and marketing innovative medical equipment & devices. Healthcare providers also need to support initiatives on innovation by the medical devices companies by enabling the testing of and awareness for the products shared among the stakeholder community including patients.

Overall, there is great potential in the medical equipment and device industry in Bangladesh. Favorable policy and regulatory measures for the medical devices industry have the potential to create an enabling environment that would set the direction for large scale indigenous manufacturing of various types of medical devices. However, the pace of its growth will depend on the regulatory framework and providing favorable policy support. The Government's role as a policymaker supporting the manufacturing of medical devices will have a significant impact on the growth of the industry.

1 Background and Objective

1.1 Background

Bangladesh has been experiencing rapid economic growth along with a steady increase in population during the last decade. Driven by the rising income of the population as well as the gradual shift in disease profiles from communicable disease (malaria, typhoid, hepatitis B and C, measles, etc.) to non-communicable diseases (cardiovascular disease, cancer, disease, etc.), demand for healthcare services has been growing swiftly in Bangladesh. Furthermore, an outbreak of the COVID-19 pandemic has further compounded the demand for certain types of medical services subsequently the demand for related medical equipment/ devices.

To meet the increasing demand of the population, the Bangladesh government has been diligently working towards developing and improving medical facilities including hospitals, diagnostic centers and clinics in cooperation with the private sector. In parallel to the development of medical facilities, demand for medical equipment/ devices has been growing rapidly during the recent years. However, the demand has been largely met by imports (around 92% as of 2019). While the local production of medical equipment/ devices is currently at a nascent stage and largely limited to consumables products such as syringes, needles, bags and personal protective equipment (PPE) and a few electrical/ electronic appliances, there is a huge potential to increase local production of medical equipment/ devices. Potential foreign and domestic investors have been waiting for further market expansion or for improvement in the regulatory environment.

Considering the current condition of healthcare services sector and the increasing need for medical treatment and diagnosis (partly owing to the changes in disease profile, i.e., to non-communicable diseases), all of which have been complicated by the continued COVID-19 pandemic, BIDA decided to undertake the study on the medical equipment/ devices sector in Bangladesh in order to understand the current situation and identify the future prospects of medical equipment/ devices industry.

1.2 Objective

The study aims to propose a roadmap for promoting the medical equipment/ devices sector in Bangladesh. The roadmap shall state the vision for the development of this sector and key issues to be tackled, enlist potential segments (categories/ items) of medical equipment/ devices for investment promotion (for manufacturing in Bangladesh), and propose possible measures/ actions for attracting foreign and local investments contributing to the development and expansion of manufacturing of the potential equipment/ devices in Bangladesh.

1.3 Method

The Study has been undertaken through a combination of primary and secondary research.

Key referential documents and data:

- Health Bulletin 2019, MOHFW, Bangladesh
- Registration Guideline for Medical Devices Bangladesh 2015
- Data collection survey on the regulation concerning drugs/ medical devices in Bangladesh, March 2019
- Country report of Bangladesh healthcare-related industries, METI Japan, March 2020
- Data on the trade/ investment/ industrial production of medical equipment of Bangladesh

Interviewed organizations:

Market side (hospitals/ clinics/ diagnostic center)	
Association of hospitals, etc.	One association
Public hospitals	A few hospitals
Private hospitals	Five hospitals (tertiary and secondary)
Clinics/ diagnostic center	Three clinics/ diagnostic centers
Industry side (medical equipment/ devices manufacturers and suppliers)	
Manufacturers (cum-supplier)	Six companies
Suppliers	Nine companies
Regulator side (government)	
Regulatory agency	Directorate General of Drug Administration (DGDA) Central Medical Stores Depot (CMSD)

Summary of interviewed organizations is shown above and Appendix-1 shows the detailed list of interviewed organization.

2 Healthcare Sector In Bangladesh And Market For Medical Equipment/Devices

2.1 Overview of Healthcare Sector in Bangladesh

2.1.1 Trends in healthcare services

Bangladesh, one of the most densely populated countries in the world, has made a remarkable progress in providing healthcare services to its vast population despite constraints of healthcare resources. According to the sources, healthcare is provided by around 2,300 government medical facilities (consisting of government primary care, secondary and tertiary hospitals, medical/ dental colleges), 5,400 private hospitals/ clinics and medical/ dental colleges, 9,500 private diagnostic centers, some specialist facilities (such as chest, infectious hospitals) and a number of community clinics/ health centers.

Major healthcare sector indicators of Bangladesh (2019)

Subject	Indicators	Value
Health facilities/ Hospitals	No. of primary care hospitals (government)	2,003
	No. of secondary and tertiary hospitals (government)	255
	No. of private hospitals/ clinics	5,321
	No. of medical/ dental colleges hospitals (government)	51
	No. of medical/ dental colleges hospitals (private)	96
	No. of infectious disease control centers	5
	No. of chest hospitals	14
	No. of private diagnostic center	9,529
	No. of community clinics/ health centers	16,348
	No. of trauma center	5
Health workforce in public facilities	No. of physicians	111,413
	No. of nurses	71,369
	No. of medical technologists	5,208
	No. of medical assistants	3,709
	No. of domiciliary staff	19,830
Health services	No. of beds public-run hospitals per 10,000 population	3.3
	No. of doctors per 10,000 population	1.55
Health financing	GDP spent on healthcare	0.92%
	Ratio of health expenditure against total government budget	5.1
	Out-of-pocket expenditure for health	73.9%
	Per-capita total expenditure on health (USD)	41.91

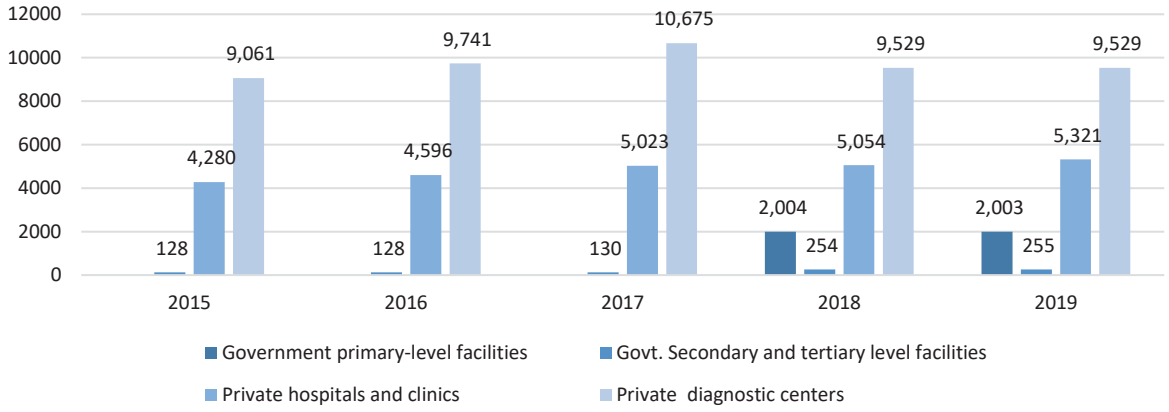
Source: Health Bulletin 2019, The World Bank Group, Financial Express

Total number of government secondary/ tertiary level healthcare facilities has increased to 255 in 2019 from 130 in 2017, and their number of beds under the Directorate General of Health Service (DGHS) has also increased significantly from 49,414 beds in 2017 to 54,660 beds in 2019.

Private hospitals and clinics have been providing a range of healthcare services predominantly for the growing middle- and upper-class patients. The number of registered private hospitals and clinics has increased to 5,321 in 2019 and the number of hospitals beds that are registered by DGHS was estimated to be around 91,537 in 2019.

In a bid to provide child and maternal healthcare, the government has established 16,438 community clinics and health centers across the country as well.

Type and number of healthcare facilities in Bangladesh

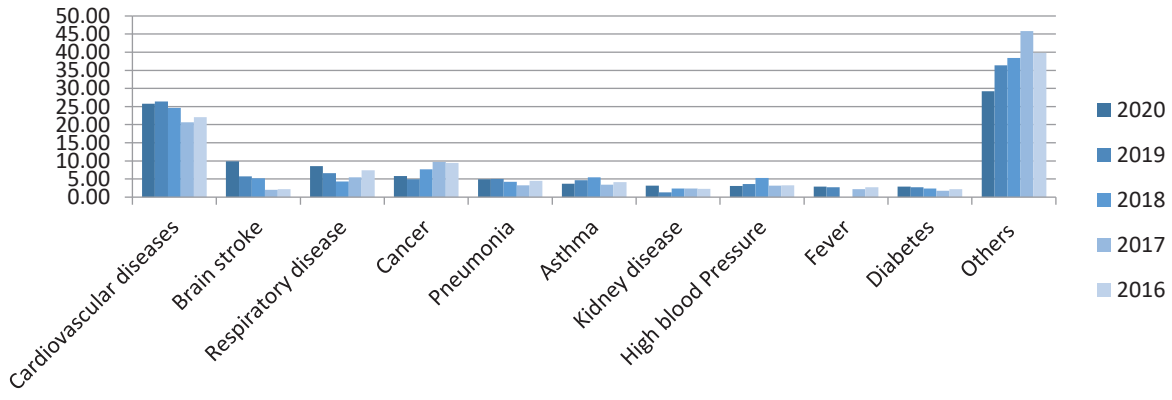


Source: Health Bulletin, DGHS

2.1.2 Trend of disease by type

In Bangladesh, communicable diseases have been dominant in terms of incidence and death, including malaria, dengue, chikungunya, zika, filariasis, tuberculosis (TB), pneumonia, cholera, hepatitis A, typhoid, human immunodeficiency virus (HIV), kalazor, soil-transmitted helminths (STH) and rabies. However, the incidence of these communicable diseases has drastically fallen since early 2000s, and the resultant death cases caused by communicable diseases has been falling as well.

Share of major cause for death in Bangladesh



Source: Bangladesh Bureau of Statistics (BBS)

Non-communicable diseases (NCDs) have been increasing rapidly in Bangladesh like many other developing countries. NCDs such as cardiovascular diseases, diabetes mellitus, cancer, and chronic respiratory diseases

were the major causes of death accounting for 67% of all death in 2018, according to an estimate by the World Health Organization (WHO) [1]. In recent years, the prevalence of heart attack and heart-related disease with brain stroke and respiratory diseases have been the major causes of death.

Brain stroke, which has recently become very common in Bangladesh, has claimed around 10% of total death at the same period while 8,248 people died due to coronavirus infections (see the Appendix-2 for the detail breakdown of causes for death in Bangladesh).

According to the Bangladesh Bureau of Statistics (BBS), around 572,349 or two-third of total death in Bangladesh in 2020 were caused by NCDs. Around 20 percent or 180,408 out of a total of 854,253 deaths during the same period were caused by heart attack. Other common diseases such as pneumonia, asthma, liver cancer and kidney diseases caused the remaining 15% of total deaths.

To tackle the increasing number of deaths caused by NCDs, the government of Bangladesh has taken various initiatives. One of the most prominent initiatives undertaken was the establishment of NCD corners at the Upazila Health Complexes in 2012. The NCD corners provide prevention and care services for the common NCDs along with screening for certain cancers.

2.1.3 Trend in development of clinical departments

Due to the increasing number of cancer-related cases, both public and private hospitals have been developing oncology department, which deal with cancer treatment from chemotherapy to surgery. Major private hospitals[2] have already set-up special oncology units. Public healthcare sector has also realized this, and the government has decided to set-up 100 bed cancer treatment units at every government medical college hospital in eight divisional cities. The government will implement this initiative to facilitate cancer treatment for the growing number of cancer patients.

Development of cardiology and neurology units, two other major clinical departments, has predominantly been taking place in the private sector. National Institute of Neurosciences and Hospitals (NINH), a state-owned facility started providing services in 2012 with 100 dedicated beds for patients with stroke.

Prevalence of burn injury is very high in Bangladesh as a result of frequent fire-related incidence. Public sector is well ahead in this segment. The government has recently commissioned Sheikh Hasina National Institute of Burn and Plastic Surgery (SHNIBPS) with 500 beds. In the private sector, one hospital (City Hospital Ltd.) provides burn, plastic and cosmetic surgery.

Central medical oxygen plant has become significant to the treatment of the COVID-19 patients. Accordingly, some major hospitals, mostly privately owned, are considering setting-up their own plants. Japan East-West Medical College Hospital (JEWMCH) has installed a central oxygen plant, whereas United Hospital is setting up a similar oxygen plant in its new hospital in Mymensingh.

2.1.4 Healthcare expenditure and medical insurance system

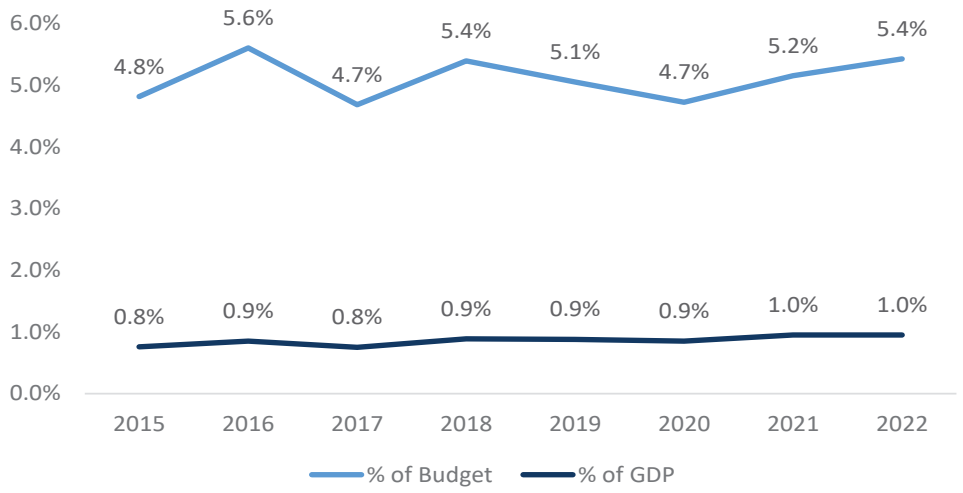
Despite a remarkable progress, historically, public health sector in Bangladesh has not received enough financial/ budgetary attention. When it comes to resources allocation, less than one percent of GDP has been allocated to the healthcare sector during the last 12 years.

1 The World Health Organization (WHO), Noncommunicable Diseases (NCD) Country Profile, 2018
2 Such as United Hospital, Square Hospital, IBN Sina and LAB AID.

In the FY2021-22 budget, healthcare sector experienced an increase by 12% compared to the previous year, which accounts for 5.4% of the total budget. According to healthcare experts, this allocation was not considered as sufficient[3] as the COVID-19 pandemic was known to have often pushedes public healthcare budget to its maximum limit.

Nevertheless, public healthcare is highly subsidized by the government, where the patients, especially for outpatient care, have to pay very minimum charges. Public-run hospitals are overwhelmed by outpatients. Health insurances whether government- or private-run is practically nonexistent. The Finance Minister expressed the government's will to expand health insurances for the wider population coverage.

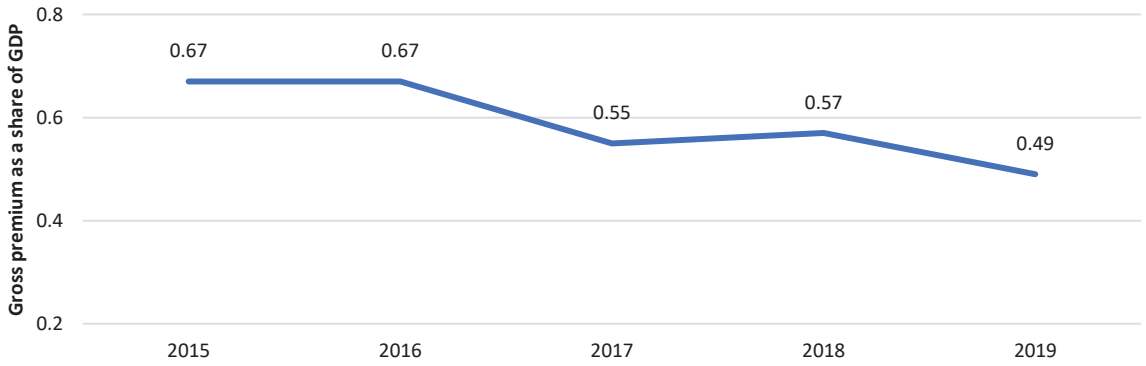
Historical budget allocation for healthcare sector as percentage of GDP/ budget



Source: Bangladesh Budget Review

Health insurance market of Bangladesh whether government- or private-run is below the global standards. Insurance penetration[4] in Bangladesh stands at 0.5%, where the average in the emerging markets is 3.3%[5]. Ratio of penetration is decreasing year on year.

Trend of insurance penetration in Bangladesh



Source: Swiss Re Institute (Sigma Reports)

3 Sujan, M.A. (2021, January 4), Ailing Health Sector: No shot in the arm, the Daily Star
4 The ratio of total insurance premiums to gross domestic product in a given year
5 Ahmed, A. (n.d.). Bangladesh's Insurance Industry Outlook for 2021: Metlife Insurance Bangladesh, July 18, 2021

Currently, there are 32 life insurance and 46 general insurance companies in operation in Bangladesh. Despite having presence of 78 companies in the market, product diversification is deemed as low[6]. Available life insurance products are mainly the whole life insurance, takaful life insurance, endowment life insurance, term life insurance and group life insurance. Non-life insurance products available in the country include investment-linked products, medical and health, and life annuity plan.

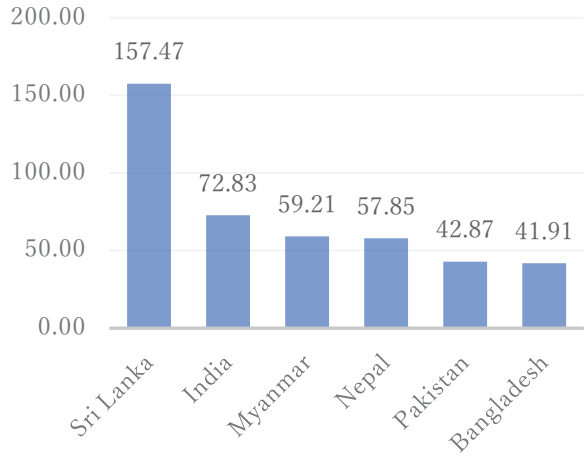
A renowned local insurance company in Bangladesh stated that their number of clients has increased after the COVID-19 outbreak. The company further mentioned that the demand for health insurance is greater from the corporate segment than individuals[7].

SSK (Shashtho Shurokkha Karmashuchi/ Health Protection Program) program under the Health Economics Unit (HEU) of the Ministry of Health & Family Welfare (MOHFW), are providing services to people who are living below the poverty line. The program provides services related to in-patient care which is manageable mostly at Upazilla and partly at district level. So far 20,391 members of 81,629 enlisted families received services till April 2021. Services under this program include;

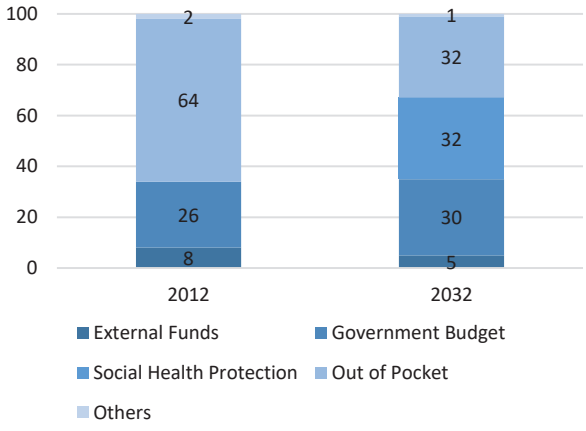
- Free physician's consultation in Upazila Health Complexes,
- Free drugs and diagnostic facilities in Upazila Health Complexes,
- Structured referral to the secondary level hospitals,
- Hospitalized SSK members will be treated according to defined medical treatment guidelines.

To achieve universal health care (UHC) by 2030, the government has also formulated a policy known as "Strategy for Finance in the Health Sector: 2012-2032".

Comparison of per-capita health expenditure among the neighboring countries (in USD)



Proposed change of financing sources for healthcare service



Source: WHO Department of Health Statistics and Informatics, World Health Statistics 2018

6 Halder, S. (May 28, 2021), Health insurance comes in handy, the Daily Star
7 Ditto.

2.2 Market System of Medical Equipment/ Devices

2.2.1 Users of medical equipment/ devices

The user of medical equipment/ devices varies among the healthcare facilities. Based on activities, capacities and role, hospitals are usually categorized into three major groups, namely, primary level, secondary level, and tertiary level.

Primary healthcare facilities include Upazila Health Complexes, TB clinics, Upazila Family Planning Office, and Maternal & Child Welfare Center (MCWC). These facilities basically function as the first contact for the people to receive health care services. Their basic role is to conduct primary check-ups and refer to the higher-level or specialized facilities if required. Some Upazila Health Complexes have clinical specialties to provide special care to the patients. These healthcare facilities usually provide treatments related to gynecology and obstetrics, dentistry, pathology and in some cases radiology and imaging.

Secondary healthcare facilities include district-level hospitals and general hospitals (typically with 100 to 250 beds). These hospitals have superior facilities and specialization compared to primary level facilities, thus providing various types of healthcare services, especially treatment for NCDs and other specialized treatments such as cardiac, neuroscience, orthopedic, etc.

Tertiary healthcare facilities include medical college hospitals, specialized institutes, maternity hospitals which are mainly located at division level. These facilities, considered to be of the highest level, provide specialized care in a wide range of disciplines, covering anesthesiology, burn plastic and reconstructive surgery, hepatology, neuro surgery/ medicine, oral and maxillofacial surgery, respiratory medicine, urology, cardiology and critical care unit (CCU), dermatology, gastroenterology, hematology/ sacrococcygeal teratoma (SCT), medicine, nephrology, pediatric nephrology, pediatric surgery, psychiatry radiology and imaging, radiotherapy, oncology, etc.

The number of private hospitals and clinics have been increasing for the last five years in Bangladesh and they use a vast quantity of medical equipment/ devices to meet patients' needs. Around ten thousand of private diagnostic centers usually offer basic pathology, x-ray, computerized tomography (CT) scan, endoscopy and ultrasonography, etc.

2.2.2 Standard set of medical equipment/ devices by facility grade

The existing three levels (grades) of hospitals and clinics require different set of medical equipment/ devices depending on their grades.

For example, 10 to 50-bed primary level hospitals, which provide treatments related to gynecology and obstetrics, dentistry, pathology and in some cases radiology and imaging, are presumed to use non-invasive devices like microscope sphygmomanometer (blood pressure machine), stethoscope, oxygen flow meter, nebulizer, etc. Invasive devices like ultrasonic scaler, micro-motor machine, light cure machine, electrosurgical unit and laryngoscope are also among the major tools required for primary level hospitals. Among the active devices, microscope, view box for x-ray, different analyzers, centrifuge, ultra-sonogram devise, are mainly used. As per in-vitro devices (IVD), glucometer is the major device used at a primary level hospital.

Appendix-3 shows the detail set of standard medical equipment/ devices to be utilized by each grade of hospitals, while Appendix-4 shows the standard list by segment (or device type).

2.2.3 Practices of procurement and financing

Practices of procurement and financing for medical equipment/ devices differ between public and private hospitals. For public hospitals, the process is fully monitored and executed by the MOHFW, whereas for private hospitals the process is autonomous and executed by hospitals themselves.

For public hospitals, depending on their requirements or demands, the operational plan (OP) is prepared for both funding and procurement. Along with the operational plan, tender documents are prepared. For private hospitals, they compile the requirements or demands from their respective departments, and then prepare a priority list for procurement and tender. Upon the requirements for equipment/ devices, specifications for each equipment/ device are set. Public hospitals fix the specification statement during the formulation of operational plans and private hospitals set specification on their need basis.

After-sales service is an important criterion, since not all technical problems can be solved by the hospitals' inhouse engineers. Especially upon the replacement of parts, after-sales service is essential. Many hospitals (especially private hospitals) admit that availability of after-sales service plays a vital role when selecting the suppliers.

Procurement practices of medical equipment/ devices by different type of hospital

Primary hospital	Secondary & tertiary hospital	Private hospital & clinic
Collect requisition of product from the UHC	Invitation for and Submission of tenders	Get requirement from user departments
Prioritize the product	Forming Tender Evaluation Committee and Tender Opening Committee	Advertise for quotation
List of suppliers	Evaluation of tender	Get quotation from vendor and make comparative statement
Advertise for bidding	Preparation and approval of Tender Evaluation Report (TER)	Place order
Receive tendered bids	Contract awards	Open LC for Importing Equipments
Compare bids with the market price	Delivery/ completion of contract and Payment of bills	Through CNF agent release equipment from port
Make comparative statement and pricing.	Complaints handling, Contract amendment, and Contract dispute resolution	Install at the hospital
Award contract to the lowest bidder		
Get approval from the director general		

For public hospitals, the MOHFW through the central procurement unit known as Central Medical Stores Depot (CMSD) purchases medical equipment/ devices by utilizing the following funds;

- Development budget backed-up by the operational plan,
- Non-development budget,
- Goods purchased and supplied by development partners (donors),
- Fund provided by the institution itself.

Private hospitals use funds from their own revenues. For imported items, they import equipment/ devices through opening the letter of credit (L/C) from any scheduled banks. In general, public health insurance system does not contribute to purchase/ expansion of medical equipment/ devices.

On the other hand, interviewed hospitals observed the following as issues in procuring medical equipment/ devices;

- Difficulty or delay in timely releasing imported devices from customs (although the customs admit to the poorly prepared documents from the importer's side). Sometimes, it takes almost two months to release those imported devices.
- Difficulty in ensuring regular maintenance for the devices particularly for public hospitals which do have little in-house technicians. For periodic maintenance or upon the case of major repairing, hospitals usually enter annual maintenance or comprehensive maintenance contract.
- Reliance on imported (spare) parts from original manufacturers or overseas market for replacement for imported devices, thus taking considerable time to import (spare) parts and affecting the process of treatment to the patients.

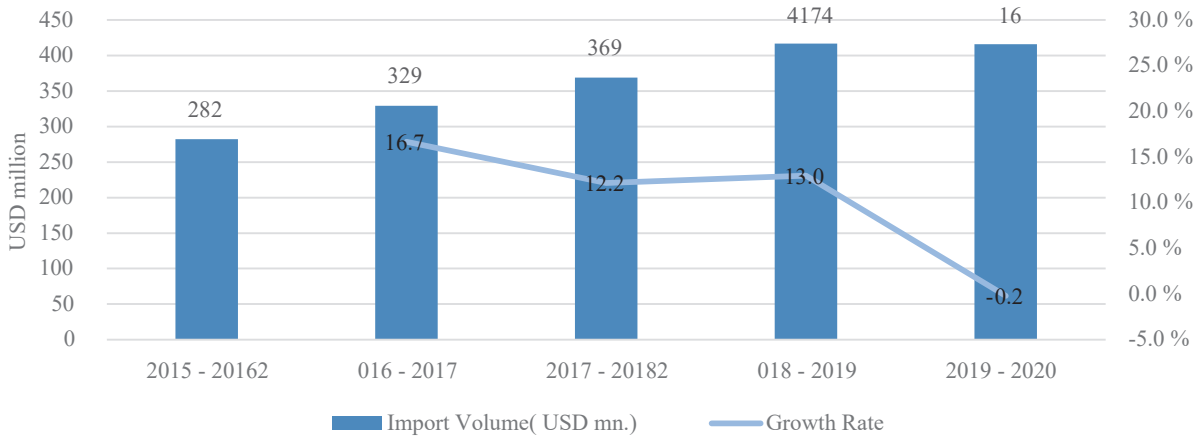
2.3 Market Size, Trends and Demand of Medical Equipment/ Devices

2.3.1 Size of market, import of medical equipment/ devices

Medical equipment/ device imports in Bangladesh

Medical equipment/ devices market in Bangladesh is dominated by import. According to the interviews with selected hospitals, except some disposable items and minor equipment, medical equipment/ devices have largely been imported from the USA, EU, China, Japan. According to the Bangladesh Bank (BB), almost USD 416 million worth of medical equipment/ devices were imported during FY2019-20. Even though the amount remained constant from the previous year (USD 417 million in FY2018-19), import of medical equipment/ devices have been steadily increasing at a compounded annual growth rate (CAGR) of 10.2% during the last five years.

Import trend of medical equipment/ devices (in USD million)



Source: Bangladesh Bank

Among the imported equipment/ devices, those related to physical and chemical analysis (for example, polarimeters, refractometers, spectrometers, gas or smoke analysis apparatus viscosity, porosity, expansion, surface tension measuring equipment) has accounted for the largest share. Other largely imported equipment/ devices include catheters, electoro-diagnosis devices (for example patient monitor), magnetic resonance imaging (MRI) devices, CT scan devices, ultrasonic scanning devices, measuring or checking instruments/ appliances (for example, glucose-meter, blood pressure measuring machine, etc.). Equipment/ devices required for oxygen-therapy and artificial respiration have also recorded increasing trend of import during the last five years.

Apart from these equipment/ devices, some others have showed a remarkable growth in terms of annual import value. Between FY2017-18 to FY2019-20, import of intravenous (IV) cannulation increased by almost 166.2% on a CAGR basis. IV cannula works as any other needle to draw blood or provide medicine through vein. Other than IV cannula, import of the following devices has recorded a remarkable growth;

- Optical instruments (increase by 88.6%),
- Therapeutic respiration apparatus (69.2%),
- Device for measuring or detecting ionizing radiation (48.2%),
- Blood lancet (47.4%),
- Other syringes (47.3%),
- Plastic syringe with or without needles (44.6%),
- Thermometers and pyrometers parts and accessories (43.1%).

An outbreak of the COVID-19 has been directly or indirectly accountable for such a remarkable growth of import, thus increasing the demand and the resultant import of IV cannula, therapeutic respiration apparatus, thermometers and pyrometers in FY2019-20, which are considered to be directly related to the COVID-19.

Import for scalp vein set has also increased as government has been focusing on burn units and plastic surgery units. Import of optical instruments like microscopes has also been increasing as the number of tests/ research related services increases. With the growth of diabetic patients, demand for blood lancet has been growing as well.

Appendix-5 shows the detailed import data of medical equipment/ devices.

2.3.2 Demand for medical equipment/ devices in Bangladesh healthcare sector

For the purpose of providing healthcare (covering medical and clinical cares) by even small clinics, various types of equipment/ devices are required. Increase of medical centers directly impacts the demand for medical equipment/ devices even though it is episodic. The Bangladesh government has been working to increase the number of medical centers. Not only the public sector, but also the private sector has been trying to increase the number of medical facilities. Because of this, it is expected that demand for medical equipment/ devices in Bangladesh would remain high for a certain period.

Examples of government and private initiatives in expanding the healthcare facilities is give below;

Government initiative: The Bangladesh government has been taking various initiatives to provide low-cost medical services to the lower- and middle-income classes, such as;

- Establishment of 287 zone-base public hospitals with 50 beds in Dhaka, Gazipur and Narayanganj by 2025,
- Establishment of 100-bed full-fledged burn/ plastic surgery units in eight divisional towns,
- Expansion of Dhaka Medical College Hospital with 2,500 beds to a 5,000-bed hospital,
- Establishment of 100-bed cancer treatment units at public medical colleges in divisional towns.

Private initiative: Private sector started to emerge in healthcare sector since 1990s, and currently their medical facilities exist at over 5,300 private hospitals/ clinics and 9,500 diagnostic centers in the country. In 2019, 267 new hospitals and clinics were established, which has created a significant demand for medical equipment/ devices.

Medical equipment/ devices with strong demand in Bangladesh can be categorized into a few segments depending on their usage and applied departments of medical care facilities;

Consumable/ disposable items are required in all clinical departments. Consumable/ disposable items are represented by such items as alcohol pad (blood bank), blood bag, imaging film, dialyzer F6 HPS (hepatopulmonary syndrome), cannula, mask, acriflavine betadine solution, etc.

Hospital furniture is also very essential for all medical care facilities. Dressing trolley, hospital bed (manual or electric), instrument trolley, isolation screen stand, IV stands/ hooks/ poles, laboratory table, mayo stand/ trolley, medicine trolley are among the major ones in this segment.

The main cause of death in Bangladesh has been changing from communicable diseases to NCDs in recent years. Furthermore, while the Bangladesh government has been emphasizing on the development of treatment for both cancer and burn-patients, the private sector has been placing greater focus on cancer treatment. Increasing treatment of NCDs requires more test/ examination and surgery and demand for related medical equipment/ devices.

Imaging & laboratory such as endoscopy, x-ray machine, MRI, CT scan device.

OT/ ICU equipment, such as operation theater (OT) light, diathermy, suction machine, nebulizer, syringe pump, activated clotting time (ACT) machine, CPAP (nasal continuous positive airway pressure) machine, defibrillator, oxygen generator, patient monitors.

The COVID-19 started to spread in Bangladesh since March 2020. This pandemic has proved that the current healthcare infrastructure is not sufficient to handle the situation. The COVID-19 has also created

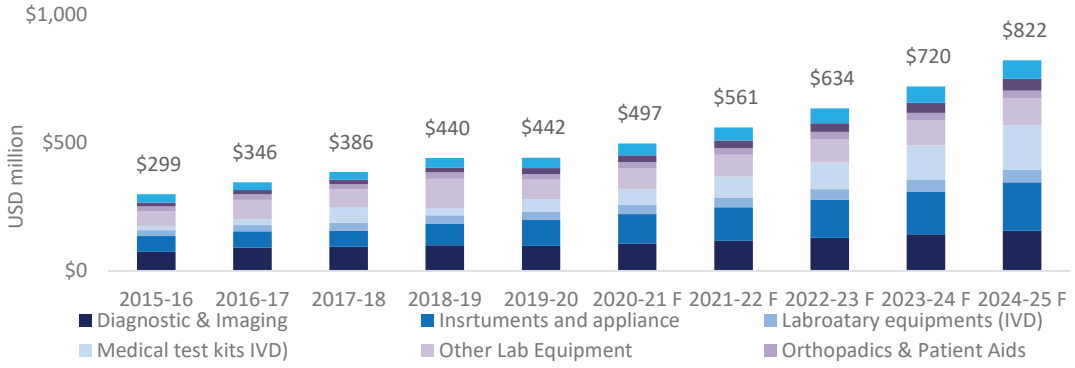
a huge demand for medical equipment/ devices in the country, where the demand for devices/equipment related to lung and cardiac diseases diagnosis and treatment increased to a great extent. Demand for patient monitor, CPAP nasal mask, ventilator, high flow nasal cannula (HFNC), oxygen flow meter has increased significantly as well. Adoption of CT scan and HRCT (high-resolution computed tomography) scan has also increased.

2.3.3 Forecast of medical equipment/ devices market expansion

The size of Bangladesh medical equipment/ devices market was estimated at USD 442 million in June 2020 and is expected to reach approximately USD 820 million by 2025[8], growing at a CAGR of 13%. The market currently is dominated by instruments/ appliances segment and diagnostic imaging equipment (in terms of value), which are expected to continue growing steadily. IVD device/ kit is also expected to be the fastest growing segment at almost 30% per annum over the next five years, followed by cardiological device (15% per annum), consumables (12%) and diagnostic imaging equipment (10%).

Increasing access to healthcare and diagnostic facilities combined with rising income of the population is expected to drive the growth of the market. Besides, high prevalence of chronic diseases, rising awareness and growing importance of early diagnosis and prevention, and increasing use of point-of-care (PoC) diagnostic, are other key factors that is expected to drive the need for medical equipment/ devices in the country.

Forecasted size of the Bangladesh market for medical equipment/ devices



Source: Bangladesh Bank import data and industries' estimate

8 One of the stakeholders concerned with this sector observes the possibility of the faster growth of Bangladesh market size than this estimate, but no data that support this observation is available. The forecast for market size is based on the 5- year historical growth rate of import and local production of individual segment of medical device & equipment combined with expected forecasted growth rate based on interviews with industry insiders.

3 Medical Equipment/ Devices Industry in Bangladesh

3.1 Overview of the Industry in Bangladesh

3.1.1 Medical equipment/ devices industry in Bangladesh

Bangladesh has a large and growing domestic market for medical equipment/ devices. However, the domestic demand has mostly been met by import. As per DGDA, only 8% of the local demand is met through local production. Currently there are only a handful of companies involved in manufacturing medical equipment/ devices in a relatively large scale. Particularly in case of sophisticated (i.e., high-tech or invasively high-risk ones) medical equipment/ devices, hospitals and diagnostic centers mostly procure from European or equivalent countries. 'Made in Bangladesh' for such equipment/ devices is not yet acknowledged by local users. However, locally manufactured consumable and disposable items such as syringe, PPE have increasingly gained popularity and market share.

At present, the sector comprises around 15-20 manufacturing companies, of which about three to four can be considered as large unit, and the remaining as small to medium sized ones. Opsonin Saline, a subsidiary of Opsonin Pharma started manufacturing consumable items during 1987. It was followed by Nipro JMI in 1998, which is currently the largest manufacturer of consumables such as syringe, infusion set, surgical products, homecare devise and sterilizers in the country with an estimated market share of over 70%. Bi-Beat, a company headed by prominent scientist Dr. Rabbani, has also been manufacturing ECG, canopy and therapy equipment and several other equipment at a small scale since 1996.

During the last decade however, an increased interest has been observed with several new manufacturing companies joining the industry. Among them, Getwell, a subsidiary of PRAN group and ANC Medical Devices are operating mainly in the consumable segment. In addition, a few more companies specializing in segments such as radiological equipment, electro medical equipment, orthopedic product, hospital furniture, In-vitro diagnostic (IVD) device have also started production at a small scale. Since the advent of the COVID-19 pandemic, a few pharmaceuticals as well as RMG/textile companies have joined the industry for producing PPE and hygiene items. According to data provided by DGDA, the industry produced less than USD 100 million worth of medical equipment/ devices in FY 2020-21. Of the total production, over 70% includes medical disposables. Some industry insiders, however estimate the actual local production to be much higher than the estimated figure.

Recently, Bangladesh has also started exporting medical devices & equipment. During FY2020-21, exports of medical equipment/ devices amounted to USD 48.8 million. Notable export items include ophthalmic devices, orthopedic devices, consumables such as syringe and infusion set, respiratory appliance/ instruments. Additionally, export of personal protective equipment (PPE) amounted to another USD 618 million during FY2020-21. (Source: EPB)

3.1.2 Recent trend of foreign investment

The relatively small manufacturing segment has been dominated by local entrepreneurs over the years. Foreign companies have been present only through joint venture with local corporations. Nipro JMI is the most prominent among them. However, during the last decade registration of foreign companies has been observed in manufacturing of disposable items, surgical equipment, orthopedic appliances, and some ophthalmic and dental instruments. Total registered foreign investment with BIDA amounted to USD 11.6 million between 2013 and 2020. In addition, in December 2020, NIPRO Corporation of Japan has

announced an additional investment of USD 15 million into JMI Group for marketing of medical equipment and medicine produced by the group. Overall, proposed FDI in the sector have been made from several countries and some foreign companies registered with BIDA are as follows;

List of registered medical equipment/ devices manufacturers with BIDA

Year	Country of Origin	Proposed projects as of registration
2013	Taiwan	Medical wears/ aprons, other disposable products
2013	U.S.A.	Disposable plastic items
2014	South Korea	Medical/ surgical equipment, orthopedic appliances, medical infusion tubes and bags
2014	Malaysia	Latex powdered/ non-powdered gloves, surgical gloves
2016	China	Flexible/ complete/ acrylic denture, metal/ porcelain crown
2016	U.S.A.	Reagents
2017	Netherlands	Ophthalmic lenses
2020	Sweden	Medical/ dental instruments and supplies

Source: BIDA

3.1.3 Rules and regulations concerning medical equipment/ devices

A regulatory regime concerning manufacturing (and importation) of medical equipment/ devices in Bangladesh has been put into effect by DGDA through the Registration Guidelines for Medical Device, Bangladesh 2015. The regulatory regime concerning medical equipment/ devices in the country has the following features;

Classification of medical equipment/ devices

As per the Registration Guideline, medical equipment/ devices are classified into the categories of A, B, C and D in accordance with their risk level.

Class	Risk Level	Example of equipment/ devices
A	Low risk	Surgical retractors/ tongue depressors
B	Low-moderate risk	Hypodermic needles/ suction equipment
C	Moderate-high risk	Lung ventilator/ bone fixation plate
D	High risk	Heart valves/ implantable defibrillator

Source: Registration Guidelines for Medical Device, Bangladesh 2015

If any product does not follow the above classification, internationally accepted classification shall be accepted by DGDA. All medical equipment/ devices classified into B, C and D needs to be registered before they are imported or manufactured in the country since products under these categories are sensitive to human lives and pertains high risk factor.

Registration of manufacturing medical equipment/ devices

When manufacturers want to produce medical equipment/ devices in Bangladesh, they (or their authorized local agents) need to register the product with DGDA. Application documents required for registration differ among the classifications of medical equipment/ devices. When manufacturers register Class-A equipment/ devices, only a declaration of conformity is required. When manufacturers register Class-B, -C and -D

devices, the manufacturers have to file the application form with details of applicants/ products (including user's manual), description of manufacturing process, marketing, sales and after-service activities. Detailed procedure for registration of product manufacturing is provided in Appendix-6 (also detailing the procedure for registration for product importation).

Upon the submission of required documents for registration, DGDA visits the factory for the purpose of inspecting the process and quality of the products concerned on a sampling basis, and certify the registration if satisfied. For manufacturing of moderate to high-risk products under category B, C & D, DGDA requires clinical evaluation and performance study of the product along with random sampling after the production line is established.

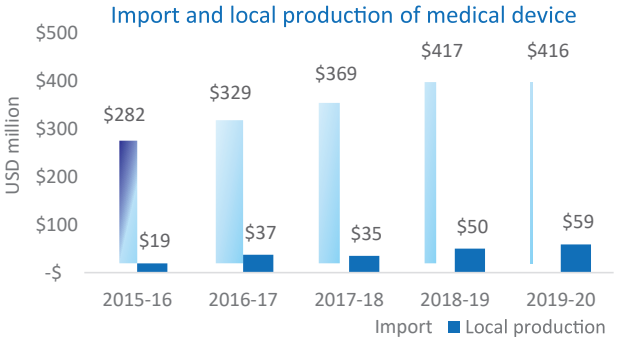
Marketing and sales

To be eligible for selling medical equipment /devices in Bangladesh, manufacturers (and importers) have to demonstrate conformity assessment along with prescribed procedure, while submitting documents such as certificate of quality management system along with ISO-13485 and etc.

3.2 Performance and Challenges of the Industry

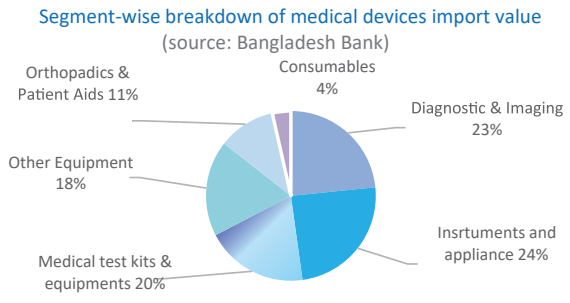
3.2.1 Trends of production and import in Bangladesh

At present, over 4,000 medical equipment/ devices are in use in the country, about 8% of which are manufactured locally. Among the locally produced items, majority are consumables such as disposable/ precision safety syringe, needle, blood bag, blood transfusion set, cannula, blood collection tube, etc. Consumables have an estimated annual market size of around USD 60 million in Bangladesh where the majority is produced locally while around USD 15 million is imported annually.



Source: Bangladesh Bank, EPB, DGDA

Aside from consumables, Bangladesh also produces orthopedic products (bone-hook, drill machine, spine retractor), surgical sterilizers, hospital furniture, home care devices such as blood pressure/ glucose monitoring device, compressor nebulizer, electro-cardiogram and other small instruments, albeit at a small scale.



The COVID-19 outbreak has enhanced local production of PPE including protective mask/ clothing, respirator, hospital gown. However, Bangladesh remains largely dependent on import for almost 92 of the demand of medical equipment/ devices in terms of value (according to DGDA). Growing at a CAGR

of 10% between 2015 and 2020, overall import of medical equipment/ devices has amounted to USD 416 million as of June 2020. While medical equipment/ devices constitute a variety of items ranging from syringe to CT scan, the overall demand has been steadily increasing.

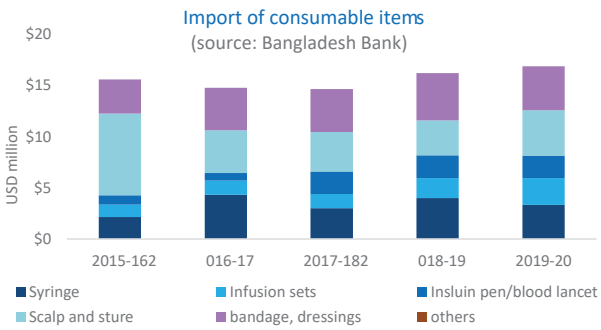
Instrument/ appliance forms the largest import segment in terms of value accounting for 24% of the total imports in FY2019-20. This segment includes a variety of items comprising ophthalmic instruments/ appliances, therapeutic/ physiotherapy appliances, respiratory apparatus, medical/ surgical sterilizer, etc. Growing at a CAGR of 19%, respiratory apparatus such as ventilator, oxygen therapy, other breathing appliance have been the fastest-growing segment, followed by therapeutic appliances.

Diagnostic and imaging devices represent the second largest import segment accounting for 23% of the overall import in FY2019-20. Growing at a CAGR of 7% since June 2015, import of diagnostic imaging devices has reached a value of USD 97 million as of June 2020. This segment constitutes items such as CT scan, MRI, ultrasound equipment, X-ray equipment, and other parts/ components. The fastest growing imported items include Electrocardiogram (ECG), x-rays and MRI, followed by ultrasound and CT scan. ECG is produced locally but at a very small scale.

Medical test kits and equipment represent the fastest growing major segment. Growing at a CAGR of 32% since June 2015, almost USD 50 million worth of such kits was imported in FY2019-20 alone. With increasing chronic and infectious diseases, demand for testing/ diagnostic kits have been increasing rapidly. The demand is fulfilled largely through import, as only 5% of IVD kits (for testing of diseases such as malaria, diabetes, dengue, the COVID-19, etc.) is produced locally. Recently, two companies have begun producing glucometer and pregnancy test kits with plans to expand further into cancer marker and blood grouping reagents.

Orthopedic, cardio and patient aids import amounted to USD 45 million in FY2019-20. This segment consists of cardio-vascular devices such as angioplasty devices (stent, guidewire, balloon), cardiac electronic implants (pacemaker, heart valve), orthopedics/ prosthetics devices, hearing aids, and hospital furniture. Vascular devices make up the largest portion in this segment, indicating an increasing need for cardiac treatment devices in the country. This is followed by hospital furniture, orthopedics products and cardiac electronic implants. Orthopedics devices are locally produced as well as exported. Hospital furniture such as multi-functional/ examination/, operation theater (OT) beds, wheelchairs are also manufactured locally but at a small scale.

Consumables (including disposables and surgical equipment) consist of various types of syringes, needle, infusion set, catheter, surgical device (suture, scalp vein, dressing, etc.). Estimated market size of consumables amounted to around USD 60 million. Major share of consumables is accounted for by locally produced items while the import amounts to an average of USD 15 million annually. Around 550 to 600 million syringes are locally produced in the country every year. The demand for consumables is expected to continue growing along with the growth in number of healthcare service providers.



3.3 Challenges faced by the industry

According to interview with selected local manufacturers (including joint-ventures with foreign investors) and importers (including agents) of medical equipment/ devices operating in Bangladesh, the following issues have been observed as outlined below. These issues have been the major factors inhibiting the growth of medical equipment/ devices manufacturing in Bangladesh as well as deterring foreign investment in the sector.

Regulatory aspect

Administration of product registration process: The overall product registration process frequently takes more than a year and subsequently creates backlog for both importers and manufacturers. Even after the product is registered, importers have to obtain indent approval from DGDA on the quantity of items to be imported. Furthermore, to make things even more complicated, the applied quantity is not always approved. (according to some interviews with importers in particular). This practice has increased the cost associated with importation (shipments).

Product inspection before registration: In order to obtain registration of manufactured devices, a manufacturer has to set up a production line from where the devices has to be randomly picked-up and then sent for testing and approval by DGDA. Such a practice of "before-registration" inspection (while acknowledging the necessity of such an inspection to administratively ensure the quality and minimize the risk associated with the equipment/ devices) necessitates manufacturers to invest their capital in setting-up the production line before the product is approved increasing the risk of capital loss and deterring smaller manufacturers.

Pricing regulation (MRP: Maximum Retail Prices): DGDA sets the maximum retail prices (MRP) on about 117 medical devices for a few specific group of locally manufactured medical equipment/ devices and provides indicative prices for all other categories of products after bargaining with manufacturers. Although manufacturers request DGDA to revise the MRP periodically, DGDA seems static on this matter. Existence of MRP causes difficulty for manufacturers, especially when the prices of raw materials (such as polypropylene = PP, polyvinyl chloride = PVC, polyethylene = PE) increases in the global market, since local manufacturers cannot instantly pass on such cost-up of materials due to the MRP. Since there are no such restrictions on the retail prices of imported devices, manufacturers recognize further difficulty in competing with imported devices..

"Local preference" in government procurement: Although according to DGDA guidelines, local manufacturers are supposed to get preference during public procurement in reality the product specifications are usually prepared in such a manner that it inhibits local manufacturers from participating in the tender process. In fact, for certain groups of devices, MOHFW and CMSD require products to have US-FDA approval even after manufacturers obtain DGDA (that is actually equivalent to US-FDA) approval, and approvals from Institute of Epidemiology, Disease Control & Research (IEDCR); getting US-FDA approval is not cost effective for manufacturers. Moreover, public procuring authorities locks out local manufacturers by specifying the 'country of origin' during the procurement tendering processing and do not place preference to local manufacturers. As a result, public procurement has been rather dominated by imported devices.

Taxation aspect

Tax structure: Existing tax structure is deemed unfavorable for local manufacturers, where the VAT applicable for locally manufactured equipment/ devices is set higher than that of imported ones in some

cases. Lower VAT is charged on some imported devices such as syringe drivers, needles, catheters, balloons, stents, electro-cardiographs and etc. There is also advanced income tax (AIT) of 5% during import of raw materials and 7% (previously 5%) during sales. Manufacturers hardly have access to rebate for this AIT, and as a result the effective tax rate becomes much higher than that applicable for importers.

The following table illustrates the list of locally manufactured products which has to compete with imported products of the lower total tax incidence (TTI);

Sample list of locally manufactured products competing with imported ones of the lower TTI

Sl.	Name of product	TTI*	Sl.	Name of product	TTI*
1	ICU/ CCU/ Hospital Bed	15%	2	Nebulizer Mask, KN 95 Respirator, Sterile Disposable Scalpel	15%
3	Various Surgical Suture	15%	4	Baby Incubator	20%
5	Atraumatic Needle for Nerve Block	21%	6	Autoclave	26%
7	Diagnostic/ Lab Reagents	31%	8	Blood Grouping Reagents	31%
9	Medical, Surgical or Veterinary Furniture	31%	10	OT Light (Halogen Lamp)	31%
11	Weight Scale	31%	12	Insulin Syringe	37%
13	20ml/ 50ml/ 60ml Disposable Syringe	37%	14	IV Cannula	37%
15	Scalp Vein Set	37%	16	Blood Transfusion Set	37%
17	Various Catheter, tubes, Umbilical Cord Clamp, Burette Set, etc.	37%	18	Disposable Feeding Tube	37%
19	Disposable Suction Catheter	37%	20	Urine Drainage Bag	37%
21	Blood Lancet	37%	22	First Aid Bandage	37%
23	Sterile Latex Surgical Gloves	37%	24	Alcohol Prep Pad	37%
25	Blood Tubing Set for Hemodialysis	37%			

** Breakdown of Total Tax Incidence (TTI) is given in Appendix-7*

Import duties for key imported raw materials: Manufacturers are not entitled to attractive concessional duties for imported raw materials. Import duties for some key raw materials used in medical equipment/ devices manufacturing such as PP and PVC are around 31%. Accordingly, without duty exemption or reduction for such materials, interviewed manufacturers admit difficulty in competing with the same imported items.

List of raw materials (for medical equipment/ devices manufacturing) of high TTI upon import

Sl.	Name of raw material	TTI*	Sl.	Name of raw material	TTI*
1	Stoppers, Caps and Lids.	128%	2	Various Iron/ Steel Bars and Rods	90%
3	Polymer Propylene, Printed Film	74%	4	N-woven Fabrics Alcohol Prep Pad	59%
5	Honing Powder	59%	6	Combination Seal for Vials	59%
7	Self-adhesive PVC Film for Bandage	43%	8	Silicon Tube	37%
9	Aseptic Pack Paper/ Aluminum Foil	37%	10	Blood Lancet	37%
11	Grinding Stone	37%	12	T-connector	37%
13	Poly Vinyl Chloride (PVC)	31%	14	High Density Polyethylene (HDPE)	31%

Sl.	Name of raw material	TTI*	Sl.	Name of raw material	TTI*
15	Thermo Plastic Rubber (TPR)	31%	16	Polypropylene (Injection Grade)	31%
17	Linear Low-Density Polyethylene (LLDPE)	31%	18	Acrylonitrile Butadiene Styrene (ABS)	31%
19	Polyacetals	31%	20	Luer Needle with Plastic Protector	31%
21	PVC Film Non-Printed (UDB)	31%	22	FEP Tube	31%
23	Blister Paper Weighing 40-150 g/m2	31%	24	Epoxy Resin	31%
25	Isoprene Latex Tube	31%	26	Silicones in Primary forms	31%
27	Gasket	31%	28	Roll Stock Tyvek Paper	31%
29	Sticker/ Label for Infusion Set	31%	30	Paper Separator	31%
31	Non-Woven Fabrics for Blood Drip Chamber	31%	32	Parts of Burette Set	31%
33	Hubs & Caps for Needle Cannula	31%	34	Solenoid Valve	31%

** Breakdown of Total Tax Incidence (TTI) is given in Appendix-8*

Tax-exemption to finished medical equipment/ devices: In the latest budget (FY2021-22), import of many finished medical equipment/ devices were tax-exempted. Local manufacturers state that such a decision is deemed against local manufacturing and instead acts in favor of finished imported equipment/ devices in finished forms and is likely to discourage investment in the sector of the country.

Import/ production aspect

Customs clearance: Customs clearance: Many industry personnel have revealed that some of the customs officials have limited knowledge about medical equipment/ devices, which causes delays in handling and processing during clearance of imported equipment. As a result, life-saving medical equipment/ devices requiring spare parts becomes non-operational for a longer period. Customs is also reported to impose duties that are inconsistent with the relevant statutory regulatory orders (SROs), thus causing unnecessary confusion and delays. Overall delay in the customs clearance process incurs demurrage charges for importers.

Shipping cost: In addition, increased shipping cost due to the COVID-19 pandemic has caused further woes to the industry. Prior to the COVID-19 pandemic, shipping cost per container was around USD 1,000, but has risen to around USD 4,500 as of June 2021. As per a report by UNCTAD, the root cause of the rising prices has been attributed to lack of shipping containers due to pandemic related logistical challenges and changes in consumption and shopping patterns triggered by the pandemic[9].

Access to stable utilities and logistic infrastructure: Many interviewed manufacturers have acknowledged a lack of access to stable utility services and logistic infrastructure, stating that access to stable supply of gas in particular has become increasingly difficult and the electricity cost has been ever increasing. In the last ten years, power tariffs have been hiked seven times and Industrial power tariff (flat rate) has increased by 143%[10]. Poor roads and worsening traffic condition have also made physical transportation to and from factory areas time consuming, thus reducing productivity. It was also noted that manual product handling by the cargo terminal operators sometimes led to damages to sophisticated devices.

Skilled workers and technical expertise in R&D: Although cheap and competitive labor is available in the country, interviewed manufacturers have faced difficulty in hiring workers with adequate technical

9 https://unctad.org/news/shipping-during-covid-19-why-container-freight-rates-have-surged
10 https://www.bpdb.gov.bd/bpdb_new/index.php/site/page/1ef6-f75a-8bd8-18f7-288a-7cd4-3881-35ef-9d8b-00b9

skills. Existing polytechnical institutes in the country are creating electromedical technologist, however, there is lack of certified biomedical & clinical engineers and technicians in the country. Device specific skilled manpower has to be created based on the need of the industry as the medical device industry is very diverse in terms of complexity of technology. Transfer of technical know-how, that is enabled through the joint venture cooperation with foreign investors, are deemed essential for development of medical equipment/ devices industry in the country.

There is also a lack of technical expertise specially in R&D, which is reflected by the low number of entrepreneurs in the sector. R&D costs during product development is usually high and expertise mobilization from foreign countries further increases such a cost, thus stressing the need for FDI attraction associated with the technical/ skills transfer to the local partners and technical capacity development in the country.

Collaboration between industry and academia: Furthermore, Research and Development done through academic institutions such as Bangladesh University of Science & Technology (BUET), Military Institute of Science & Technology (MIST) are not integrated with the industry and there is no existing standing policy to enforce such integration. As a result, the local industries are deprived of the research and product development already done through these institutions. Any technological product needs to go through stages of development and requires continuous R&D. Unless technological knowledge and expertise is dispersed and stakeholders/ manufacturers are given support through institutional collaboration and workable policies, the medical device manufacturing sector in the country will not prosper.

Maintenance/ after-service aspect

Timely after sales services to imported devices: In case of imported devices, the users in Bangladesh usually prefer internationally-acknowledged brands with well-established local after-service set-up. Multi-national companies (global brands) are conscious about their brand management and locally establish quality after-service with own technicians for maintenance and related technical support to the users. However, when it comes to a major breakdown of medical equipment/ devices, only overseas resources held by multi-nationals can deal with such events, where spare-parts are to be imported through lengthy process (otherwise, the equipment/ devices need to be sent to the country of manufacturer for repair through lengthy re-export process). As a result, there seem to be a number of malfunctional devices left unutilized for lack of repairing options (otherwise, disposed).

Supporting institution/ industry aspect

Dedicated institution for product testing/ certification: Currently there is no dedicated laboratory in the country for testing and certifying medical devices as per ISO 7886-1, ISO 7886-3, ISO 7886-4, ISO 10555-1 & 5, ISO 7864, ISO 9626, ISO 8536, ISO 8537, ISO 10993-4/5/10/11/12, etc. As a result, manufacturers have to send their products abroad for international certifications such as CE. There are some ISO-17025 accredited laboratories enlisted by DGDA which are only for the certification of Personal Protective Equipment (PPE). Some interviewed manufacturers faced issues during their product certification process since locally available testing facilities are sometimes unaware of the codes and standards to follow, thus inhibiting their product development and launch in a timely manner.

Supporting/ backward-linkage industries: There is a lack of local supporting/ backward industries for the medical equipment/ devices sector. Parts/ components used in the manufacturing of product have largely been imported from China. Molds/ dies have to be made from China or Korea as well since local molds are not suitable for providing good finishing. In Bangladesh, JMI group has its own backward affiliate

(JMI Hospital Requisites Ltd.) which produces and supplies various parts for its own consumption and for other manufacturers. Development of medical equipment/ devices sector needs to be in tandem with the development of its supporting/ backward industries to some extent.

Lack of access to finance/capital: The medical equipment device and equipment industry is capital intensive. Innovators of medical equipment//devices as well as new entrepreneurs find it difficult to market their products as traditional banks do not provide the necessary capital at reasonable cost. In addition, there is also a lack of equity-based financing in the country. Overall, the unavailability of low-cost financing options hampers innovators & entrepreneurs from successfully commercializing their products.

3.4 Market Observation and Product Localization by the Industry

3.4.1 Market observation by existing local manufacturers

Bangladesh has a large and growing market for medical equipment/ devices. Demand for these products in general has been increasing and is expected to grow in almost all categories, as a greater number of the population are able to access either advanced or average healthcare services due to increased income and affordability, and through increased number of healthcare facilities established in large cities and throughout the country.

Key demand driver: While the local production of medical equipment/ devices is currently at a nascent stage and limited to mostly medical consumables/ disposables, there is a huge potential to expand the manufacturing localization as the market size increases. Overall, the following trend will be driving the demand for medical equipment/ devices;

- Growing affordability of the population combined with increasing healthcare providers is expected to give rise to demand for medical equipment/ devices required in standard hospital and diagnostic centers. To encourage establishment of more healthcare facilities outside Dhaka, the government has recently declared fiscal incentives specific for new hospital establishment outside Dhaka. This is expected to boost the demand for medical services, as it is estimated that 40 to 60% of hospital set-up cost is spent on medical equipment/ devices.
- Changing disease profiles with shift to NCDs covering cardio disease, cancer, chronic kidney disease in particular which require specific equipment/ devices as well as general surgery with long-term treatment is expected to boost the demand for specialized medical equipment/ devices.
- Prevalence of the COVID-19 is expected to increase the demand for respiratory appliances, diagnostic imaging procedures such as CT scan and x-ray as well as PPE and hygiene items. In addition, a rise of tele-healthcare service has made it easier to reach out to a vast majority of the population which is also expected to augment the demand for medical equipment/ devices. For example, testing facilities can now send reports to radiologist located in cities overcoming the shortage of physicians in rural areas to some extent. In addition, the growing number of diagnostic and path labs outside Dhaka combined with the greater awareness among the population is expected to increase more diagnostic testing needs.

Growth potential: While the medical equipment/ devices market in Bangladesh is currently dominated by import, several new manufactures have been recently joining the sector eyeing its growth potentials. Along with the COVID-19 outbreak, demand for healthcare services has started to grow considerably. Overall capacity of hospital and diagnostic facilities is being augmented to meet such increasing demand. Currently, industry insiders have been observing a relative growth potential in intensive care unit (ICU) and OT

equipment, IVD kits such as medical test kits/ reagents, consumables such as syringe, surgical equipment, radiological equipment (low-tech), therapy appliance, laboratory sterilizer, PPE, hygiene products, hospital furniture, implants (cardiac vascular device, hearing aid), etc.

While the industry expects the demand for overall medical equipment/ devices to continuously grow at a rate 10% at least in the near future, IVD is expected to grow at a faster rate of 29%, diagnostic imaging and cardiological devices at 15% each, and lab equipment at over 10 to 12% over the next five years.

Export market: While exports of medical equipment/ devices currently account for a small percentage compared to the overall export of the country, the growth trend has been promising so far. Growing at CAGR of 42% between 2015 and 2021, exports of medical equipment/ devices (excluding PPE) reached around USD 49 million during FY2020-21. Major export items comprise instruments and appliances (USD 18.6 million), followed by ophthalmic devices (11.7 million), orthopedic devices (7.9 million), respiratory appliance (4.3 million) and consumables.

Major export destination includes Turkey, Poland, Canada, USA, Germany. Notably, the COVID-19 pandemic has considerably influenced exports. The surge in demand for respiratory instruments and syringe has seen a year-on-year increase of around 800% in export of these items.

In addition, following the outbreak of the COVID-19, PPE devices such as mask, glove have seen a significant rise in demand in the domestic market as well. Bangladesh with the production capacity and experience in ready-made garment has been successfully repurposing to produce PPE by expanding or converting existing production facilities in response to the shortage as a result of the COVID-19 pandemic.

According to Export Promotion Bureau (EPB) data, Bangladesh exported PPE worth USD 618.3 million in the FY2020-21, up from USD 501 million in the previous fiscal year, a growth of 23.4 percent. The earnings from PPE were dominated by full-body woven suits impregnated with plastic (USD 329 million), followed by medical protective gears (132.9 million), textile face masks without a replicable filter (105.6 million), and three-layer surgical masks (14.4 million).

Overall, with the global demand for medical equipment/ devices expected to reach USD 671.5 billion by 2027 with a CAGR of 5.2% from 2020 to 2027 (according to Precedence Research), the prospects of further export growth from Bangladesh look encouraging especially for PPE, ophthalmic devices, respiratory apparatus and consumables.

3.4.2 Future investment plans by existing manufacturers and suppliers (foreign and local)

Along with the above-stated market observations, existing manufacturers (both foreign including joint-venture and local) of medical equipment/ devices in the country have plans for investment, either through the expansion of their production capacity, or diversification of their product lines with new products.

According to interviews conducted, several manufacturers (100 % locally owned as well as joint venture with foreign partner) have plans to expand their product range in the future. In addition, among the current supplier/importers of medical devices & equipment, two companies (potential joint venture between foreign and local partner) have plans to venture into manufacturing some products locally. Moreover, two more suppliers (one foreign agent and another locally owned) have expressed interest in manufacturing, however their plans depend on improvement and upgradation of existing policies and improvement of business environment prevailing in the sector.

Potential Product for manufacturing: Several manufacturers have plans to expand into consumables such as syringes, needles, IV canula in response to the need arisen by the COVID-19 and associated vaccine program. Categories of interest for further domestic manufacturing include consumable/ disposable items largely, followed by in-vitro test kits/ reagents, a range of electro-equipment (low-tech), OT and ICU equipment and hospital furniture. At the same time, some multi-national and Bangladeshi companies involved in import-sales in the country are also expressing their interests in local production of some equipment/ devices.

Some of these ongoing and planned investments are summarized below;

Category	Products indicated for localized production in the future (according to the interview)	Target market
Consumable/ disposable items	Various types of syringes/ needles (including IV cannula), Catheter, Bag (blood, urine, colostomy, medical garbage), Infusion set, Heart-lung pack, Cardioplegia delivery set, Blood collection tube, Laparoscopy set, Breathing circuit, Anesthesia face mask, PPE Surgical items: Endo-surgery suture, sterile surgical glove, surgical blade, disposable scalpel, endotracheal tube, stapler	Domestic/ export Domestic
IVD kits/ reagents	In-vitro biological and molecular test kits for diseases such as tropical infectious diseases, sexually transmitted diseases and drug abuse, Cardiac marker, C-reactive protein test kit, Tumor marker test kit, Miscellaneous test kit (pregnancy test kit, diabetic glucose test strip) Various blood grouping reagents, Enzymes and potentiators as well as accessories used in blood-grouping including card-tile/ storage solution	Domestic
Imaging & laboratory	Assembly of endoscopy, x-ray, MRI, CT scan, analyzer/ washer/ mixer (hematology/ biochemistry/ chemiluminescence/ electrolyte)	Domestic
Orthopedic	Locking plates and screw systems for orthopedic implants, Plaster of Paris	Domestic
Electro-medical equipment (low-tech)	Patient monitor, Pulse oximeter, ECG, x-ray viewing box, Nebulizer, Fluid warner, Electronic stethoscope, Phaco emulsifier machine, Pulse electro-magneticfield device, device for oxygen/ aerosol therapy, Respiration apparatus	Domestic
OT/ ICU equipment & hospital furniture	Diathermy machine, OT light/ table, ICU monitor/ ventilator/ suction/ autoclave/ beds, breathing circuit Hospital furniture including general bed, trolley, table, locker, cabinet, etc.	Domestic
Vascular device	Stents, Balloons, Guidewire	Domestic

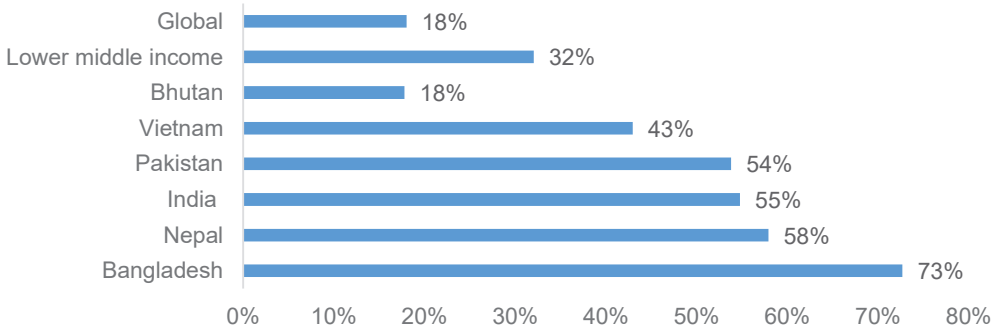
However, the respondent companies acknowledge that access to technical knowhow and finance with reasonable costs (indicated by existing manufacturers) and favorable policies including fiscal incentive

(indicated by both foreign and local manufacturers) would affect the decision and level of manufacturing of medical equipment/ devices. Current tax structure, in particular, favors imports of finished medical equipment/ devices as the high import tax on raw materials used for medical equipment/ devices makes import of finished products cheaper compared to local manufacturing. (see Appendix 7 and 8 for detailed tax rates on imported equipment/ devices and raw materials).

In addition, the absence of some other key factors for manufacturing of medical equipment/ devices in the country, consisting of time-bound (predictable) product registration regime, internationally compatible product standards, laboratory/ quality testing institution, and supporting (mold and dies) industries, has also been deterring potential foreign manufacturers (who currently supply the products to Bangladesh market through the import-sale agents) from locally manufacturing their products (according to the interviews with existing import-sale agents in the country).

Apart from that, small size of the market (in terms of per-capita healthcare spending, stood at USD 42 in 2018, lower than most regional peer countries) for relatively sophisticated, high-tech and large equipment/ devices (such as MRI, CT scan) also hamper potential manufacturers from locally manufacturing (even importing) these products in spite of the large population. Small size of health insurance penetration (0.6%) among the population has also supported this observation. Notably, Bangladesh has one of the highest out of pocket expenditure for health care spending in the world, recording at 73% of total healthcare expenditure compared to the regional and global rates of 32% and 18% respectively

OOPE rate against total healthcare spending, 2019



Source: The World Bank Group

4 Proposed Roadmap for Medical Equipment/ Devices Sector Development

4.1 Vision of the Sector Development

The Bangladesh medical equipment/ devices sector will acquire the capability of manufacturing and supplying most of the items, which belong to the relatively lower risk-level categories in view of import substitution, mainly ranging from the Class-A to -B (according to DGDA guidelines) in short- to mid-term. Whereas in mid- to long-term, this sector will expand the range of locally manufacturing items up to the relatively higher risk-level categories of the Class-C to -D by further reducing the reliance on import and contributing to diversification of the exportable items from the country.

4.2 Strategy for the Vision Attainment

To attain the said vision of medical equipment/ devices sector development, the concerned stakeholders of both private and public sectors in Bangladesh shall adopt the following strategies;

- Attraction of potential foreign investors
- Facilitation of reinvestments by existing investors,
- Easing of regulatory and operational environment specific to the sector
- Development of skills/ technology for product development and manufacturing

4.3 Potential Segments for Manufacturing Localization and Investment Promotion

The stakeholders consulted in this study basically shared their views that Bangladesh can start its quest for producing medical equipment/ devices in the country with the products belonging to the relatively lower risk-level categories, mainly ranging from the Class-A to -B (according to DGDA guidelines) at least in short- to mid-term (i.e., forecastable term). The following segments (such as consumables, hospital furniture, some items of IVD kits/ reagents, OT/ ICU equipment and some disease-specific devices)/ products in particular are considered to have the potential for local manufacturing and investment promotion.

Segment	Products for local manufacturing/ investment promotion in short-term	Risk category
Consumables	Syringes/ related items (such as IV cannula, pump), Infusion sets, Bags for variety usages, Needles, Tubes, Catheter, Daily disposables, (such as bandage, dressing,)	A, B
	PPE such as protective mask/ clothing, respirator, hospital gown, glove	A
	Basic surgical items (such as scissors, scalpels, forceps, clamps, needles, sutures, suctions, retractors, staplers and clips, spatulas, dilators, graspers, cutter instrument)	A
Hospital furniture	Beds/ tables for variety usage, wheelchairs, cabinets, lockers, trollies	A
IVD kits/ reagents	Kits for personalized tests covering glucometer, diabetic, pregnancy, blood grouping, etc., and rapid/ molecular diagnostic tests covering those employing the methodology such as DNA/ RNA, and those for various infectious diseases and fertility hormones, cardiac/ tumor/ cancer markers, COVID, drug abuse, etc.	B (inc. C)
	Reagents including common biochemistry reagents such as glucose, creatinine	A

Segment	Products for local manufacturing/ investment promotion in short-term	Risk category
OT/ ICU equipment	OT equipment including sterilizers (such as autoclave), diathermy, anesthesia equipment, OT light/ table/ switcher, etc.	B
	ICU/ life-support equipment including patient monitor, ventilator, suction, high-flow nasal cannula, oxygen flow meter, CPAP mask, etc.	B (inc. C)
Therapeutic equipment	Physiotherapy-related devices such as muscle stimulator, auto traction, pulse electromagnetic-field device, oxygen/ aerosol therapy device	B
Other equipment	X-ray, Endoscopy device	B
Orthopedic equipment	Bone hooks, drill machine, spine retractors, scapula plates, etc.	B
Disease-specific devices	Diabetic: glucose monitor, diabetic strip, blood lancet, insulin-pen	B (inc. C)
	Heart disease: ECG, vascular devices (stents, balloons, guidewire, heart valve), pacemaker, patient monitor, pulse oximeter, stethoscope echocardiogram,	B (inc. D)
	COVID-19: respiratory apparatus, nebulizer	B

Demand for **consumables** including **disposables** is expected to continue growing along with the growth in number of healthcare service providers. While the majority of these items are produced locally, there is ample room for further expansion. With the vaccination program for the COVID-19, demand for syringes/ related items (such as IV cannula) would increase significantly in Bangladesh as well as globally. In addition, demand for infusion set, bags for variety usage (blood, urine, colostomy, laparoscopy, medical garbage, etc.), needles (blood collection, biopsy, huber, spinal), tubes, catheter, and daily consumables (such as bandage, dressing) is also projected to grow rapidly. With the advent of the COVID-19 pandemic, demand for PPE including protective mask/ clothing, respirator, hospital gown, glove have exponentially been growing exponentially.

While Bangladesh produces a number of **surgical equipment**, local production of these items can be further expanded. Combined with the growing number of cardiac surgery and others such as obstetrics and gynecology, orthopedics, demand for basic surgical equipment such as scissors, scalpels, forceps, clamps, needles, sutures, suctions, retractors, staplers and clips, spatulas, dilators, graspers, cutter instruments would increase. Global market for surgical instruments is also expanding fast. Valued at USD 9.3 billion in 2020, it is expected to grow at a CAGR of 9.8% from 2021 to 2028 (according to Grandview Research).

Along with the increasing number of hospitals, clinics, diagnostic centers, demand for **hospital furniture** such as beds/ tables for variety usage, wheelchairs, cabinets, lockers, trollies would experience rapid growth. This has been evidenced by the import of hospital furniture growing at CAGR of 11% since June 2015 and hovering around USD 10 million in June 2020. While a few local companies have entered the market, there is ample room for further expansion.

IVD kits/ reagents represent one of the fastest growing segments. Moreover, due to the COVID-19 pandemic and the resultant increasing demand for testing, new diagnostic centers have been opened-up in the country to increase the absorbing capacity. With diagnostic centers growing at a CAGR of 9% between 2012 and 2019, demand for testing service would parallelly increase rapidly. IVD kits for the following needs and reagents can be localized in short- to mid-terms.

- Personalized tests covering glucometer, diabetic, pregnancy, blood grouping, etc.
- Rapid/ molecular diagnostic tests covering those employing the methodology such as DNA/ RNA, and those for various infectious disease (hepatitis B & C, HIV, influenza) and fertility hormone (pregnancy, ovulation, menopause), cardiac/ tumor/ cancer markers, the COVID, drug abuse, etc.
- Reagents including common biochemistry reagents such as glucose, creatinine.

Low-tech instruments/ appliances can be also considered for local assembly, particularly for the following (relatively) low-tech equipment (instruments and appliances):

- OT equipment: With the increasing need for surgery, demand for sterilizers (such as autoclave), diathermy, anesthesia equipment, OT light/ table/ switcher, etc. is expected to grow.
- ICU/ life-support equipment: With the expanding number of ICU facility, demand for patient monitor, ventilator, suction, high-flow nasal cannula, oxygen flow meter, CPAP mask will grow rapidly.
- Therapeutic equipment: Sedentary lifestyle can boost expansion of this segment, leading to the need for physiotherapy-related devices such as muscle stimulator, auto traction, pulse electromagnetic-field device, oxygen/ aerosol therapy device.
- Endoscopy equipment: Around 200,000 patients are newly diagnosed with cancer annually in the country. Endoscopic device is deemed as one of the preferred ways for screening cancer as well as gastrointestinal diseases, leading to increased demand for this device.

Orthopedic devices: Although Bangladesh has been consistently producing (and exporting) orthopedic devices worth USD 5 to 7 million annually since 2015, including bone hooks, drill machine, spine retractors, scapula plates, etc., these items can be further localized to substitute import.

Disease-specific devices: Increasing incidence of NCDs such as cancer, diabetes, cardiovascular, kidney is anticipated to rise in Bangladesh as diets and lifestyle of the population changes. Such changing disease profiles subsequently lead to the demand growth for equipment/ devices used for screening, diagnosis, treatment and monitoring of NCDs.

- **Diabetic:** A cross-sectional survey on NCD risk factor (by Nipsum in 2018) in Bangladesh found that 13% of the population is deemed diabetic. Subsequently demand for diabetic diagnosis and treatment devices such as glucose monitor, diabetic strip, blood lancet, insulin-pen is expected to increase.
- **Heart disease:** There is a huge demand for equipment related to diagnosis and treatment of heart disease such as ECG, stents, balloons, guidewire, reflecting the rise of incidence in the country. While the medium price range of ECG machine is assembled locally at a small scale, larger instruments are imported. In Bangladesh, an estimated 15,000 stents are used in interventional cardiac procedure such as angioplasty/ stenting while another 11,000 bypass surgeries are conducted in a year. Other equipment used for cardiac treatment such as heart valve, pacemaker, patient monitor, pulse oximeter, stethoscope, echocardiogram is expected to see a rise in demand and have potential for localization. While one local manufacturer plans to produce stents in the near future, all cardiac related devices are currently imported.
- COVID-19: Respiratory equipment, nebulizer.

4.4 Proposed Measures/ Actions for Investment Promotion (for potential/ priority products)

To promote manufacturing of medical equipment/ devices in short- to mid-term, it is essential to proactively attract both foreign and local investments to this sector and also pay attention to the existing investors in the sector in view of facilitating their reinvestments plans(expanding or diversification of their existing businesses), while making an effort to develop skills/ technology of local human resources for product development and manufacturing, ideally through partnership or collaboration with foreign manufacturers. At the same time, it is deemed important to ease regulatory and operational environment specific to this sector in view of ensuring predictable and smooth establishment of investments in particular.

Accordingly, to realize the vision of the sector development as stated above, the relevant stakeholders of Bangladesh (government, academic and private organizations) are advised to consider and render the following policy measures and actions, covering i) attraction of potential foreign manufacturers, ii) facilitation of reinvestments by existing investors, iii) development of skills/ technology, iv) easing of regulatory and operational environment specific to the sector, and v) others, for each of short- to mid-term and mid- to long-term perspectives.

Proposed policy measures/ actions (short- to mid-term perspective):

To attain the short- to mid-term vision that Bangladesh medical equipment/ devices sector acquire the capability of manufacturing and supplying most of the items, which belong to the relatively lower risk-level categories in view of import substitution, mainly ranging from the Class-A to -B.

Category	Recommended measures/ actions	Responsible institution(s)	Timeline
i) Attraction of investment by the foreign potential manufacturers	To conduct a series of business dialogue (online) with the existing foreign suppliers of medical equipment/ devices to Bangladesh market to explore the potential of investmenting in local manufacturing. * Existing foreign suppliers of medical equipment/ devices are to be introduced by local import-sales agents or Bangladesh Medical Instrument & Hospital Equipment Dealers & Manufacturers Association.	BIDA	Short-term
	To extend follow-up activity to potential investors of the sector through CMS for providing information/ inquiry services and facilitating their decision-making for investment, which were identified among the participants of promotion seminars.	BIDA	Short-term If potential investors are identified.
	To approach the registered investors in medical equipment/ devices sector, and facilitate in solving their problems which is hindering materialization of their registered investment plan, through a series of dialogue.	BIDA	Short-term
	To propose manufacturing of medical equipment/ devices (to be picked-up among the potential products for indigenous manufacturing and investment promotion as proposed above) as an industrial undertaking entitled with corporate income tax exemption/ holiday. * Ideally without placing condition for local contribution in early stage of manufacturing.	National Board of Revenue (NBR)	Short-term Upon the annual revision of the Finance Act.
ii) Facilitation of reinvestments for existing investors	To approach the existing investors in medical equipment/ devices sector to explore the possibility of reinvestment (for expansion or diversification), and facilitate in solving their problems in materializing their reinvestment plans, through a series of dialogue. * Existing investors with reinvestment possibility are to be identified by investment monitoring unit and facilitation services to be provided through Aftercare Unit of BIDA.	BIDA	Short-term
iii) Development of skills/ technology for product dev./ manufacturing	To facilitate technology transfer (technical license/ know-hows/ assistance) through income tax deduction against the expenses for receiving license/ know-how/ assistance from foreign manufacturers or participating in external technical training.	NBR	Mid-term
	To facilitate development of skilled manpower by academic institutions by offering accredited certified courses and training programs in the field of biomedical and clinical engineering as per the need of the industry.	BUET, MIST, DU, DGDA	Short-term
	TTo facilitate academia and industry collaboration on research and product development, through relevant policy formulation.	BUET, MIST, DU, DGDA	Short-term
	To introduce 'Incubation Lab', a certified medical device lab where innovators can come and develop their devices.	MIST, BUET	Short- to mid-term

Category	Recommended measures/ actions	Responsible institution(s)	Timeline
iv) Easing of regulatory & operational environment specific to sector	To establish a dedicated (separate) unit/wing in DGDA to oversee all processes related to medical device and equipment including product registration and approval process, testing, calibration and certification process, quality control of manufacturing process and performance monitoring.	DGDA	Short-term
	Capacity building of DGDA by involving bio-medical engineers/ experts in different processes of DGDA.	DGDA	Short- to mid-term
	To make product registration process of medical equipment/ devices more efficient and manufacturer-friendly at least for those categorized as Class-B.	DGDA, Relevant stakeholders	Short- to mid-term
	To finalize the "Guideline for Medical device and Equipment Manufacturing".	DGDA	Short-term
	To periodically review maximum retail prices (MRPs) of medical equipment/ devices produced by local manufacturers, based on manufacturers' request for revising MRP (when the prices of key materials increase in particular).	DGDA	Short-term
	To enforce "local preference" during public procurement and encourage local manufacturers to participate in public tenders through clarifying the standards to follow, while accepting local standards/ certifications (by DGDA/ IEDCR, etc.) for locally manufactured devices and relaxing "the country of origin" requirements placed in the procurement process.	CMSD, DGDA	Short- to mid-term
	To introduce and activate mobile court or teams to regularly raids the market for unregistered and illegally imported products and impose fines accordingly.	DGDA	Mid-term
	To establish a dedicated laboratory in collaboration with academic institutions for testing/ certifying medical device & equipment as per applicable international standards and accredited by global regulatory authority (Including WHO)	DGDA, Relevant stakeholders	Mid-term
	To revise tax (VAT) and duty regime and make them manufacturer-friendly reducing VAT/ import duties applicable to key materials (including PP, PVC) for certain period of 5 to 10 years from the commencement of commercial production.	NBR, Ministry of Industries	Short-term
	To reduce the ratio of AIT upon importation of key materials/ parts utilized by medical equipment/ devices manufacturers, while ensuring operation of rebate system of AIT.	NBR	Short- to mid-term
	To consider provision of concessional capital/ working capital loans at lower interest rates with more accessible terms of conditions (e.g., longer grace/ repayment period), which are specific to the sector (only for new investment projects).	Bangladesh Bank (BB)	Mid-term
v) Others	To recognize medical equipment/ devices industry as an industrial undertaking in the Industrial Policy	Ministry of Industries	Short-term
	To widely announce among the medical equipment/ devices manufacturers that Bangladesh Association for Medical Devices & Surgical Instruments Manufacturer & Exporter (BAMDSIME) was established.	BAMDSIME	Short-term

Proposed policy measures/ actions (mid- to long-term perspective):

To attain the mid- to long-term vision that Bangladesh medical equipment/ devices sector expands the range of locally manufacturing items, up to the relatively higher risk-level categories of the Class-C to -D in view of further lessening the reliance on import and contributing to diversification of the exportable items from the country.

Category	Recommended measures/ actions	Responsible institution(s)	Timeline
i) Attraction of investment by the foreign potential manufacturers	To organize sector-specific investment seminars on medical equipment/ devices in countries having expertise in manufacturing medical equipment devices such as USA, Germany, Japan, South Korea, etc.	BIDA	Mid- to long-term
iii) Development of skills/ technology for product development/ manufacturing	To support funding of R&D activities by medical equipment/ devices manufacturers through sponsorship, grants, etc. To facilitate access by medical equipment/ devices manufacturers to existing R&D facilities for product development purpose. To encourage development of innovative medical devices, processes, business R&D activities can be provided tax incentives/credit.	DGDA, Council of Scientific & Industrial Research NBR	Mid- to long-term Mid- to long-term
iv) Easing of regulatory and operational environment specific to the sector	To improve cargo handling at customs/ container terminal area to protect sophisticated parts for medical equipment/ devices, To furnish cold storage facility to accommodate imported materials of bio-chemical nature (used for manufacturing of medical equipment/ devices). To assign a DGDA representative (drug super) to ports to help with identification of equipment and reduce time required for customs clearance.	Chittagong Port Authority, Dhaka Intel. Airport DGDA	Mid- to long-term Long-term
	To curb illegal importation of unregistered medical equipment/ devices through tightening the border management.	NBR	Mid- to long-term
	To provide cash incentives on export of medical equipment/ devices.	Ministry of Commerce	Mid- to long-term
v) Others	To help Bangladesh Association for Medical Devices & Surgical Instruments Manufacturer & Exporter (BAMDSIME) to enhance its capability of policy advocacy.	BAMDSIME Ministry of Commerce	Mid- to long-term
	To expand health insurance coverage among the general public.	IDA	Mid- to long-term

Appendixes

Appendix-1: List of interviewed hospitals, clinics/ diagnostic centers, medical devices industries

Hospitals, clinics/ diagnostic centers		
No.	**Name**	**Remarks**
1	United Hospital	General hospital (private)
2	Japan East West Medical College Hospital/ Ship Aichi Medical Services	General/ specialized hospital (private)
3	Ahsania Mission Cancer and General Hospital	General/ specialized Hospital (private)
4	Ibu Sina Hospital	General hospital (private)/ Diagnostic center
5	LABAID Specialized Hospital	Specialized hospital (private)/ Diagnostic center
6	Holy Family Red Crescent Medical College	General hospital (public: medical college)
7	Bangladesh Medical Association	Association for doctors

Medical equipment/ devices industries				
No.	**Name of Company**	**Type**	**Foreign/ Local**	**Main products/ brands**
1	Bi-Beat Ltd.	Manufacturer	Local	ECG machine, canopy, etc.
2	Celltron EMS	Manufacturer	Local	Electro medical equipment Aporajoya (brand)
3	National Electrocare (Pvt) Ltd.	Manufacturer	Local	Equipment for physiotherapy, laboratory & operation theatre
4	OMC Healthcare (Pvt) Ltd.	Manufacturer	Local	Testing kit (PCR test for COVID-19)
5	JMI Group*	Manufacturer	JV with Japan, UK, South Korea	Consumables
6	Promixco Limited	Manufacturer	Local	Hospital furniture & Consumables
7	ZAS Corporation	Supplier	Local	Consumables
8	Siemens Healthcare Limited	Supplier	Subsidiary of German company	Radiology, Cardiology, Lab Equipment, Cancer Therapy
9	Meditech Imaging Ltd.	Supplier	Local	Imaging related equipment
10	Becton Dickinson India Pvt Ltd	Supplier	JV with US company	Consumables
11	Globex Marketing Company	Supplier	Local	Laboratory, ophthalmology, dental, microscope
12	Agappe Diagnostic Switzerland GMBH	Supplier	Subsidiary of Switzerland company	Instruments and reagents
13	Meril Bangladesh (Pvt) Ltd.	Supplier	Subsidiary of Indian company	Testing Kit, Surgery equipment
14	Johnson & Johnson Medical	Supplier	Subsidiary of US company	Operation theatre related equipment/ devices
15	Medtronic Bangladesh (Pvt) Ltd.	Supplier	Subsidiary of US company	Life-saving medical devices

** Including JMI Syringes & Medical Devices Ltd., JMI Hospital Requisite Manufacturing Ltd., NIPRO JMI Co. Ltd.*

Appendix-2: Percentage of major causes for death in Bangladesh

Diseases	2016	2017	2018	2019	2020
Heart attack	16.20	16.20	10.40	17.80	20.80
Brain stroke	2.20	2.00	5.20	5.70	9.90
Respiratory disease	7.40	5.50	4.30	6.60	8.60
Cancer	9.40	9.70	7.70	4.90	5.80
Heart disease	5.90	4.50	14.20	8.60	5.00
Pneumonia	4.50	3.30	4.20	5.00	4.90
Asthma	4.10	3.40	5.50	4.70	3.70
Kidney disease	2.30	2.40	2.40	1.30	3.20
High blood pressure	3.30	3.20	5.30	3.60	3.10
Fever	2.70	2.20	-	2.70	2.90
Diabetes	2.20	1.80	2.40	2.70	2.90
Paralysis	-	-	-	1.20	1.50
Road traffic accident	2.20	2.70	2.50	1.50	1.40
Malnutrition	-	-	-	2.10	-
Geriatric	-	-	3.70	-	-
Jaundice	-	1.30	3.20	-	-
Tuberculosis	-	-	2.10	-	-
Dysentery	-	-	1.30	-	-
Old age	18.60	17.90	-	-	-
Drowning	1.80	1.60	-	-	-
Others	17.20	22.30	25.60	31.70	26.30

Source: http://www.bbs.gov.bd/site/page/ef4d6756-2685-485a-b707-aa2d96bd4c6c/

Appendix-3: Standard sets of medical equipment/ devices by hospital/ clinic grades

Primary level hospitals

Class	Non-invasive device	Invasive device	Active device	In-Vitro device
A	Micropipette, Sphygmomanometer (BP machine), Stethoscope, Trolley, Thermometer, Height & weight scale, Pulse oximeter, Labor table, Thyroid protector, Gonad protector		Microscope, Water bath, Refrigerator, View box for x-ray, OT light, LED	
B	Oxygen cylinder, Oxygen flow meter, Nebulizer	Ultrasonic scaler, Micro-motor machine, Light cure machine, Electrosurgical unit, Laryngoscope	Analyzer, Colorimeter (digital), Centrifuge, Ultrasonogram	

Class	Non-invasive device	Invasive device	Active device	In-Vitro device
C		Suction machine	ECG machine, Resuscitation unit, Anesthetic machine, CTG (Cardiotocography) machine, Auto-processor for x-ray, X-ray (analog)	Glucometer
D				

Secondary level hospitals with 250 beds

Class	Non-invasive device	Invasive device	Active device	In-Vitro device
A	Micropipette, Sphygmomanometer (BP machine), Stethoscope, Trolley, Thermometer, Height & weight scale, Pulse oximeter, Labor table, Thyroid protector, Gonad protector	Saw plaster cutting (electric and manual)	Microscope, Water bath, Refrigerator, View box for x-ray, OT light, LED, Plasma Storage, Freezer, Gonioscope, Retinoscope, Ophthalmoscope, Colposcope	
B	Oxygen cylinder, Oxygen flow meter, Nebulizer	Ultrasonic scaler, Micro-motor machine, Light cure machine, Electrosurgical unit, Laryngoscope, Pharyngoscope, Tympanometer, Otoscope, Hysteroscope, Laparoscopic surgery set, Phaco-emulsifier, Tonometer, Laser yag	Analyzer, Colorimeter (digital), Centrifuge, Ultrasonogram, Treadmill for exercise tolerance test, Intravascular ultrasound, Automated blood culture, Immunochemistry analyzer, Fetal doppler, CTG machine, Autorefractor-keratometry, B-scan, ocular, ultrasound, Magnetic resonance imaging, Fluoroscopy	
C		Suction machine	ECG machine, Ventilator, Resuscitation unit, Anesthetic machine, Patient Monitor, CTG (Cardiotocography) machine, Auto-processor for x-ray, X-ray (analog), Automated external defibrillator, Cardiopulmonary resuscitation (automated), Syringe pump, Infusion Pump, Temporary pacing equipment, Incubator, Urodynamic machine, C-arm machine	Glucometer
D				

Tertiary level hospitals with 500-beds

Class	Non-invasive device	Invasive device	Active device	In-Vitro device
A	Micropipette, Sphygmomanometer (BP machine), Stethoscope, Trolley, Thermometer, Height & weight scale, Pulse oximeter, Labor table, Thyroid protector, Gonad protector, Bucks traction set, Cervical traction set, Holter Tractional set, Pelvic traction set, Splint braun bowler, pH meter, Tongue depressor, Striper blood bag	Saw plaster cutting (electric and manual), Gauge cutting machine	Microscope, Water bath, Refrigerator, View box for x-ray, OT light, LED, Plasma storage, Freezer, Gonioscope, Retinoscope, Ophthalmoscope, Colposcope, Motor table mounted, Magnifying loupe binocular, Microscope Immuno-fluorescent, DNA extraction system automated, RNA extraction system, Auroscope, Bronchoscope, Esophagoscope, Pleuroscopy	PCR conventional set
B	Oxygen cylinder, Oxygen flow meter, BiPaP machine, CPaP machine, Nebulizer	Ultrasonic scaler, Micro-motor machine, Light cure machine, Electrosurgical unit, Laryngoscope, Pharyngoscope, Tympanometer, Otoscope, Hysteroscope, Laparoscopic surgery set, Phaco-emulsifier, Tonometer, Laser yag, Proctoscope, Endoscope, Enteroscope, Duodenoscope, Dilator esophageal savory galliard, Snare polypectomy, Needle sclerotherapy endoscopy, Dilator ballon achalasia, Dental implant kit, Arthoscopy machine for TM surgery, Ventose machine, Stone punch, Resectoscope, Urethrotome, Uretero-renoscope, Lithotriptor, Extra corporeal shock wave lithotripter, Percutaneous nephroscope set, STENT Endobronchial	Analyzer, Colorimeter (digital), Centrifuge, Ultrasonogram, Treadmill for exercise tolerance test (ETT), Intravascular ultrasound, Automated blood culture, Immunochemistry analyzer, Fetal doppler, CTG machine, Autorefractor-keratometry, B-scan, ocular, ultrasound, Magnetic resonance imaging, Fluoroscopy, Cone beam computed tomography, Amalgamator mechanical, Casting machine for dental, B-scan ocular ultrasound, Laser argon, Pachymeter, Ophthalmic unit, Electro-encephalography (EEG), Electro-myography (EMG), Analyzer hematology, Electrophoresis capillary auto, Continuous passive mobilizer (CPM), Shortwave therapy unit, Shockwave therapy unit, Ultrasound therapy unit, Laser therapy unit, Tense device, Muscle stimulator, Massage vibrator, UV therapy unit, Occupational therapy unit, Interferential therapy (IFT) unit, Electro convulsive therapy (ECT) machine, Bone material densitometer (BMD), Iontophoresis machine, Uroflowmetry machine, Electric dysfunction treatment device	Chamber macleod for semen analysis

Class	Non-invasive device	Invasive device	Active device	In-Vitro device
C		Suction machine	ECG machine, Ventilator, Resusciation unit, Anaesthetic machine, Patient monitor, CTG (Cardiotocography) machine, Auto-processor for x-ray, X-ray (analog), Automated external defibrillator, Cardiopulmonary resuscitation (automated), Syringe pump, Infusion pump, Temporary pacing equipment, Incubator, Urodynamic machine, C-amr machine, Colonsocope video set, Ultrasound endoscopic, Hydrogen breath test machine, Angiogram, NCS (nerve condition study) machine, Mammography	Glucometer
D				

Appendix-4: Detailed list of equipment/ devices used by each segment (or device type)

Radiology and imaging related devices

Class	Non-invasive device	Invasive device	Active device	In-Vitro device
A				
B			1.5 Tesla MRI, Dental ultrasonic scaling, Ultrasound machine, CT scanner	
C			Defibrillator, Electrocardiogram (ECG), Echocardiography, Exercise tolerance test (ETT) machine, X-ray machine	
D				

Critical care unit related devices

Class	Non-invasive device	Invasive device	Active device	In-Vitro device
A	Pulse oximeter, Cidex tray		Infant warmer, Phototherapy LED	E.P.O.C blood analysis
B	BiPaP machine, CPaP machine, Nebulizer	Diathermy machine, Laryngoscope		
C		Suction machine, Vacuum pump	Baby incubator, Defibrillator, Infusion pump, Syringe pump, Ventilator, Patient monitor, ACT machine	
D				

Operation theatre related devices

Class	Non-invasive device	Invasive device	Active device	In-Vitro device
A			OT light, C-arm machine	
B	Oxygen cylinder flowmeter, Vacuum regulator with jar, Nebulizer	Diathermy machine, Laryngoscope		Suction machine
C			Multi parameter monitor, Anesthesia machine with ventilator, CTG machine - fetal monitor & doppler, Laparoscopy machine, Syringe pump, Defibrillator	
D				

Physiotherapy related devices

Class	Non-invasive device	Invasive device	Active device	In-Vitro device
A	Quadriceps chair, Lumbar & cervical traction, Static bicycle, Shoulder wheel, Dumbbell/ blocks, Physio ball, Exercise mats, Height/ weight scale, Exercise pulley			
B			Shortwave therapy unit, Ultrasound therapy unit, Laser therapy unit, Tense device, Muscle stimulator, Massage vibrator	
C				
D				

Hospital furniture

Class	Non-invasive device	Invasive device	Active device	In-Vitro device
A	Baby blood collection bed, Baby cot, Blood collection chair, Blood collection table, Bowl stand, Crush cart trolley, Delivery bed (Gyne), Dressing trolley, Hospital bed 3 function manual, Hydraulic hospital bed, Instrument trolley, Isolation screen stand, Laboratory table, Mayo stand/ trolley, Medicine trolley, Padiatric bed, Patient stretcher, Saline stand, Scrub attire trolley, Wheelchair		Hospital bed 3/4 function electric, View box 1 film (LED)	
B				
C				
D				

Laboratory & blood bank related devices

Class	Non-invasive device	Invasive device	Active device	In-Vitro device
A	BP machine, First aid box		Binocular electron microscope, Biosafety cabinet, Blood bank refrigerator 2-8 c, Coagulation analyzer, Electrolyte analyzer, Elisa machine, Emergency charger light, ESR analyzer, Microtome, Photoelectric colorimeter, Plasma freezer, Platelet agitator, Water bath, Weight machine	
B			Biochemistry analyzer, Blood bag sealer machine, Blood cell separator, Blood collection monitor, Blood culture system, Blood mixer rotator, Centrifuge, hba1c analyzer, Hematology analyzer, Laminar air flow cabinet, Urine analyzer, Vortex mixer	
C			Incubator 37°C	
D				

Consumables/ disposable items

Class	Non-invasive device	Invasive device	Active device	In-Vitro device
A	3/0 silk cutting body, 3/0 silk packed, 3/0 silk round body, Adult BP cup, Air way tube, Anesthetic mask, Petridis, ECG chest electrode	Alcohol pad, Examination gloves	ENT head light, ENT bulb, OT light	ASO latex, Pregnancy (latex), ICT Dengue device (IgG+IgM), Immutrep RPR 500T, Immutrep TPHA 200 test, Leishmania (Kalazar), Leishmania IgG/IgM device (Kalazar), Micropath febrile antigen-brucella-abortus, MT reagent, Nitelmycin, Salmonella anti sera 2ml, Syphilis RPR reagent TPHA, TB device (40 test), Tetracyclin, TPHA latex/ strip/ device, VDRL, Widal (TO, TH, AH, BH, AO, BO), Dengue Ag (NS1) device, Dengue device (IgG/ IgM), Malaria device, Leishmania device, TB device, Vasmatic ESR device
B	Ambu bag, Anesthesia cartridge, Appendrop tube	Adson plain forceps, Adson tooth forceps, Air water turbine, Artery forceps, Fistula needle, BP blade, Dental needle, MT syringe, Disposable syringe		Pregnancy reagent kit, HCG test kit
C				Blood glucose test strip
D				HIV testing kit

Appendix-5: Import data of medical equipment/ devices

Import of medical equipment/ devices (value in thousand USD) by HS code (4 digit)

HS code	Commodity	2015/16	2016/17	2017/18	2018/19	2019/20	Share of total import	CAGR
9018	Instruments in medical, surgical, etc.	108,460	113,125	106,299	130,763	149,078	38.30%	8.28%
9027	Instruments, physical, chemical analysis etc.	49,155	60,464	59,069	89,710	65,299	16.77%	7.36%
9022	Apparatus based on x-ray, alpha, etc.	40,684	52,186	64,075	62,259	55,797	14.33%	8.22%
9019	Mechano-therapy, etc, appliances	13,466	12,000	14,674	20,679	26,742	6.87%	18.71%
9031	Measuring/checking instrument	10,636	13,361	11,981	23,637	18,885	4.85%	15.43%
9032	Automatic regulating instruments	17,589	18,309	14,699	17,468	13,724	3.53%	-6.01%
9021	Orthopedic, appliances etc.	12,032	15,054	14,250	14,695	13,561	3.48%	3.04%
9024	Machines, hardness, strength test etc.	11,921	14,014	10,683	13,478	10,575	2.72%	-2.95%
9026	Instruments, checking flow, level etc.	11,332	9,961	11,025	14,511	9,366	2.41%	-4.65%
9402	Medical, surgical, dental furniture	6,013	6,617	6,155	10,615	9,071	2.33%	10.83%
9030	Oscilloscopes, spectrum analyzers etc.	5,066	12,983	12,421	12,607	8,585	2.21%	14.10%
9025	Hydrometers, thermometers etc.	3,855	1,896	2,443	4,249	4,720	1.21%	5.19%
9020	Other breathing appliance, gas masks	1,275	3,074	707	397	2,394	0.61%	17.06%
9033	Parts/ accessories n.i.s.	1,416	1,545	2,007	1,800	1,474	0.38%	1.01%
	Total	**292,900**	**334,589**	**330,488**	**416,868**	**389,271**	**100.00%**	**7.37%**

Medical equipment/ devices import with growth (CAGR) of more than 40% (value in thousand USD)

HS Code	Commodity	2015/16	2016/17	2017/18	2018/19	2019/20	CAGR
90183914	IV cannula			136	411	964	166.2%
90314100	Optical instruments		20	70	55	130	86.6%
90191090	Therapeutic respiration apparatus	548	506	431	916	4,494	69.2%
90183915	Scalp vein set		82	72	120	274	49.5%
90301000	Measuring or detecting ionizing radiation	206	1,144	501	809	994	48.2%

HS Code	Commodity	2015/16	2016/17	2017/18	2018/19	2019/20	CAGR
90183917	Blood lancet			35	57	76	47.4%
90183190	Other syringes	24	68	114	115	113	47.3%
90183130	Plastic syringe with or without needles	51	25	28	42	223	44.6%
90259000	Thermometers and pyrometers parts/ accessories	450	704	1,211	1,583	1,886	43.1%

Medical equipment/ devices import with growth (CAGR) of 31% - 40% (value in thousand USD)

HS Code	Commodity	2015/16	2016/17	2017/18	2018/19	2019/20	CAGR
90183912	Blood transfusion set		93	199	102	250	39.0%
90184100	Dental drill engines & other dental equipment	28	275	94	87	102	38.2%
90192090	Ozone, oxygen, aerosol therapy & respiration apparatus nes.	1,175	1,435	3,117	5,972	4,173	37.3%
90181400	Scintigraphy apparatus	14	248	241	135	48	36.1%
90222100	Apparatus of alpha, beta or gamma radiations for medical, surgical, dental or veterinary uses	1,179	1,777	4,589	2,809	3,948	35.3%
90251100	Liquid-filled, for direct reading	127	94	86	158	424	35.2%
90314900	Optical instruments/appliances for measuring or checking, nes.	657	1,049	615	6,614	1,975	31.7%

Medical equipment/ devices import with growth (CAGR) of 21%-30% (value in thousand USD)

HS Code	Commodity	2015/16	2016/17	2017/18	2018/19	2019/20	CAGR
90304000	Other instruments and apparatus like cross-talk meters, gain measuring instruments, distortion factor meters, psophometers	340	4,299	1,350	718	989	30.6%
90309000	Parts/Accessories Of instruments and apparatus for measuring or detecting alpha, beta, gamma, x-ray, cosmic or other ionizing radiations.	83	190	1,527	201	228	28.7%
90181100	Electro-cardiographs	1,780	2,293	2,125	2,648	4,713	27.6%
90302000	Oscilloscopes and oscillographs	180	240	253	375	473	27.3%
90269000	Parts And Accessories of flow meters, level gauges, manometers, heat meters	561	1,045	816	1,639	1,414	26.0%
90183920	Insulin pen/ Insulin cartridge	902	760	2,178	2,181	2,130	24.0%
90213100	Artificial joints	509	1,658	255	680	1,193	23.7%
90311000	Machines for balancing mechanical parts	160	208	218	441	364	22.8%

HS Code	Commodity	2015/16	2016/17	2017/18	2018/19	2019/20	CAGR
90308900	Other instruments and apparatus for measuring or detecting alpha, beta, gamma, x-ray, cosmic or other ionizing radiations	732	718	2,723	1,132	1,643	22.4%
90189090	Other Instruments and appliances used in medical, surgical, dental or veterinary sciences	11,055	17,089	15,254	21,826	24,149	21.6%
90221900	Apparatus based on the use of x-rays, nes.	6,310	7,987	8,892	9,542	13,573	21.1%
90191020	Massage apparatus	171	267	186	367	367	21.0%

Medical equipment/ devices import with growth (CAGR) of 10%-20% (value in thousand USD)

HS Code	Commodity	2015/16	2016/17	2017/18	2018/19	2019/20	CAGR
94029090	Medical, surgical or veterinary furniture & parts thereof (excluding hospital bed	2,713	4,231	1,880	6,087	5,706	20.4%
90329000	Parts and accessories of automatic regulating devices of 90.32	537	747	1,036	1,353	1,099	19.6%
90318000	Instruments, appliances and machines for measuring or checking, nes.	7,704	9,456	9,140	12,723	15,297	18.7%
90183120	Portable infusion pump (syringe driver)	91	153	102	220	179	18.4%
90268000	Other instruments for measuring or checking variables of liquids or gas	1,224	1,219	1,818	4,030	2,366	17.9%
90183916	Suction catheter	35	76		34	66	17.2%
90200000	Other breathing appliance, gas masks	1,275	3,074	707	397	2,394	17.1%
90183110	Prefilled glass/plastic syringes	1,458	3,958	2,537	3,427	2,719	16.9%
90215000	Pacemakers excluding parts and accessories	1,850	2,740	2,500	3,521	3,420	16.6%
90183913	Feeding tube	12	17	8	51	22	16.4%
90192010	Oxygen-therapy and artificial respiration apparatus	7,766	6,553	8,867	10,127	13,868	15.6%
90303300	Other instruments and apparatus, for measuring or checking voltage, current, resistance or power without a recording device	1,002	2,201	1,169	1,624	1,734	14.7%
90303200	Multimeters with a recording device	164	114	1,237	212	264	12.6%
90221300	Apparatus based on the use of x-rays, nes, for dental uses	572	616	756	864	918	12.6%
90321000	Thermostats	3,041	3,202	3,153	5,349	4,876	12.5%
90189020	Kidney dialysis machines/baby incubator	2,821	3,555	3,479	4,508	4,411	11.8%
90211000	Orthopedic or fracture appliances	956	861	1,045	735	1,492	11.8%

HS Code	Commodity	2015/16	2016/17	2017/18	2018/19	2019/20	CAGR
90219010	Heart valve	525	1,215	858	850	806	11.3%
90214000	Hearing aids, excluding parts and accessories	686	1,319	1,939	1,656	1,044	11.1%
90212100	Artificial teeth	39	27	4	45	59	10.9%
90258000	Other instruments hydrometers, pyrometers, hygrometers, etc., and combinations	655	635	357	535	982	10.7%
90221400	Apparatus based on use of x-rays, nes, for medical/ surgical/ veterinary uses	10,089	15,602	25,046	19,228	14,789	10.0%

Appendix-6: Registration procedure for medical equipment/ devices in Bangladesh

Registration Guideline for Medical Device, Bangladesh 2015

All medical devices of class B, C and D, as per the below mentioned classification shall be registered before they are imported or manufactured into the country.

1. Application for registration of medical devices which are already being imported or manufactured into the country shall be made immediately from the issue of this guideline.
2. For medical devices which are to be imported or manufactured for the first time, the applicant has to apply for registration before such import or manufacture.
3. The application for registration has to be made by a local authorized person of the manufacturer or foreign supplier or authorized agent to the DGDA.

Procedure for application

1. Application for registration of a medical devices shall be made by the authorized person or local authorized agent of the manufacturer, or foreign supplier in the prescribed form to the office of the DGDA.
2. Prescribed fees of Taka _____ shall be paid along with the application.
3. Separate application and fees are to be paid for separate applications, separate manufacturing premises and separate products. Similar type of medical devices if manufactured in the same premises can be applied in the same application form (example – all stents – similar type, all intra ocular lenses – similar type, all catheters – similar type, all orthopedic implants – similar type, all sutures – similar type, etc.). However, an application shall not have more than 5 products and for more than 5 products separate applications shall be made.

Details to be submitted in the application

1. Name, address, telephone number and email of the local authorized agent,
2. Authorization letter, in original, from the manufacturer authorizing the local agent to be the applicant. This will not be required if the application is made by the manufacturers' own office in Bangladesh.
3. Name, address, telephone number and email id of the company/ person responsible for placing the product in the market, if not the same as the manufacturer. Certified by a company's legally authorized person.
4. Details of the local manufacturer in case part processing is planned to be carried out in Bangladesh.

Product Details

1. Name of the device, including brand name and generic name, if any,
2. Device class as per GHTF classification,
3. Device details and description,
4. Device sizes,
5. Principle use of the device,
6. Device master file, (required only in cases where the CE/ US FDA approvals are not available) should include material of construction and details of quantitative analysis, if required,

7. Short description of the manufacturing process. Multi-facility manufacturing details may be given, (Brief description of manufacturing process and accompanied with flow diagram),
8. Labelling and packaging details,
9. Details of accessories required for using the product, if applicable,
10. Details of any predicate/ substantially equivalent product, if applicable,
11. Standard of the product, (prevailing International standards like ISO/ ASTM (American Society for Testing and Materials)/ IEC (International Electrotechnical Commission)/ AAMI(Association for Advancement of Medical Instrumentation),
12. Device user's manual/ direction for use, labeling if any (example : instruction for use)

Marketing and Regulatory details

1. Regulatory status in the country of manufacture and in other developed economies:
   (a) For class B devices, FSC from country of origin,
   (b) For class C and D medical devices , FSC from any one of the countries – EU, USA, Canada, Australia and Japan and FSC from country of origin,
   (c) Conformity assessment certificate or equivalent certificate has to be submitted,
2. List of countries where the device is marketed.
3. Details regarding any withdrawal/ market recall initiated by the regulatory authority from the market for any reasons in the last two years.

Combination devices

1. The medical benefits of drug-device combination products should be described in detail,
2. Drugs which are incorporated with the device and have action ancillary to device, data on the drug's safety has to be given,
3. Clinical trial data of devices containing new drugs have to be submitted (refer to the new drug definition under Drug Act and Rules Bangladesh and make amendment if necessary).

Sales and post marketing process details

1. Sales, service and distribution model details of the product, (ex: direct marketing/ channel partners; service support, etc.), procedure by applicant/ manufacturer
2. Post-marketing: Adverse report handling, field action, product recalls including re-export of the product and complaint management procedure by applicant/ manufacture.

Appendix-7: List of locally manufactured products competing with imported products of the lower total tax incidence (TTI) (duty structure as of 2021-2022)

Sl.	HS Code	Name of product	CD	RD	SD	AT	VAT	AIT	TTI
1	9402.90.10	ICU/CCU/ Hospital Bed	5	0	0	0	0	5	15%
2	3006.10.00	Polypropylene suture, Silk suture, PGA Suture, Natural Collagen (Catgut) Suture	5	0	0	5	0	5	15%
3	9018.90.90	Nebulizer Mask, KN 95 Respirator, Disposable Scalpel	5	0	0	5	0	5	15%
4	9018.90.20	Baby Incubator	0	0	0	0	15	0	20%
5	9018.32.00	Atraumatic Needle for Nerve Block	10	0	0	5	0	5	21%
6	9026.80.00	Autoclave	1	0	0	5	15	5	26%
7	9018.11.00	Electro-Cardiographs	1	0	0	0	15	5	26%
8	3822.00.00	Diagnostic/ Lab Reagents	5	0	0	0	15	5	31%
9	3006.20.00	Blood Grouping Reagents	5	0	0	0	15	5	31%
10	9402.90.90	Medical, surgical or veterinary furniture	5	0	0	0	15	5	31%
11	8539.21.10	OT Light (Halogen Lamp)	5	0	0	0	15	5	31%
12	8423.10.10	Weight Scale	10	0	0	0	15	5	31%
13	9018.31.30	Insulin Syringe	10	0	0	5	15	5	37%
14	9018.31.30	20ml/ 50ml/ 60ml Disposable Syringe	10	0	0	5	15	5	37%
15	9018.39.14	IV Cannula	10	0	0	5	15	5	37%
16	9018.39.15	Scalp Vein Set	10	0	0	5	15	5	37%
17	9018.39.12	Blood Transfusion Set	10	0	0	5	15	5	37%
18	9018.39.90	3 Way Stop Cock/ Disposable Nelaton Catheter, Disposable Stomach Tube, Disposable wound drain tube, Umbilical cord clamp, burette set	10	0	0	5	15	5	37%
19	9018.39.13	Disposable Feeding Tube	10	0	0	5	15	5	37%
20	9018.39.16	Disposable Suction Catheter	10	0	0	5	15	5	37%
21	9018.39.30	Urine Drainage Bag	10	0	0	5	15	5	37%
22	9018.39.17	Blood Lancet	10	0	0	5	15	5	37%
23	3005.10.00	First Aid Bandage	10	0	0	5	15	5	37%
24	4015.11.00	Sterile Latex Surgical Gloves (Powdered/ free)	10	0	0	5	15	5	37%
25	4811.59.10	Alcohol Prep Pad	10	0	0	5	15	5	37%
26	9018.39.18	Blood Tubing Set for Hemodialysis	10	0	0	5	15	5	37%
27	9018.39.11	Infusion Set	25	3	0	5	15	5	59%
28	4015.19.00	Latex/ Nitrile Examination Gloves	25	3	0	5	15	5	59%

CD= Customs Duty, RD= Regulatory Duty, SD= Supplementary Duty, VAT= Value Added Tax, AIT= Advanced Income Tax, TTI= Total Tax Incidence

Appendix-8: List of raw materials (for medical equipment/ devices manufacturing) of the high TTI upon import (duty structure as of 2021-2022)

Sl.	HS Code	Name of raw material	CD	RD	SD	AT	VAT	AIT	TTI
1	3902.10.00	polypropylene (Injection Grade)	5	0	0	5	15	5	31%
2	3904.10.00	Poly vinyl Chloride (PVC)	5	0	0	5	15	5	31%
3	4002.19.00	Thermo Plastic Rubber (TPR)	5	0	0	5	15	5	31%
4	3901.10.90	Linear Low Density Polyethylene (LLDPE)	5	0	0	5	15	5	31%
5	3901.20.90	High Density Polyethylene (HDPE)	5	0	0	5	15	5	31%
6	3903.30.90	Acrylonitrile Butadiene Styrene (ABS)	5	0	0	5	15	5	31%
7	3917.23.90	FEP Tube	5	0	0	5	15	5	31%
8	3917.40.10	Silicon Tube	10	0	0	5	15	5	37%
9	3919.90.10	Self-Adhesive PVC Film for Bandage	15	0	0	5	15	5	43%
10	3920.49.30	PVC Film Non-Printed (UDB)	5			5	15	5	31%
11	4802.57.00	Other Paper weighing 40-150 g/m2	15	0	0	5	15	5	43%
12	4802.57.00	Blister Paper Weighing 40-150 g/m2	5	0	0	5	15	5	31%
13	4002.60.00	Isoprene Latex Tube	5	0	0	5	15	5	31%
14	4015.11.00	Latex Surgical Gloves	10	0	0	5	15	5	37%
15	4015.19.00	Latex Examination Gloves	25	3	0	5	15	5	59%
16	4016.93.00	Gasket	5	0	0	5	15	5	31%
17	4811.49.00	Sticker/Label for Infusion Set	5	0	0	5	15	5	31%
18	5603.12.90	Non-Woven Fabrics for Alcohol Prep Pad	25	3	0	5	15	5	59%
19	5603.13.90	Non-Woven Fabrics for Blood Drip Chamber	5	0	0	5	15	5	31%
20	9018.39.90	Hubs & Caps for Needle Cannula	5	0	0	5	15	5	31%
21	3907.10.00	Polyacetals	5	0	0	5	15	5	31%
22	3907.30.00	Epoxy Resin	5	0	0	5	15	5	31%
23	3910.00.00	Silicones in Primary forms	5	0	0	5	15	5	31%
24	3920.20.10	Polymer propylene, Printed Film	25	3	10	5	15	5	74%
25	3920.20.20	Mylar Poly	10	5	0	5	15	5	43%
26	3920.20.90	BOPP Film for Overwrapping	10	5		5	15	5	43%
27	3405.90.90	Honing Powder	25	3	0	5	15	5	59%
28	3814.00.90	Thinner	15	0	0	5	15	5	43%
29	4804.39.00	Support Card Paper	10	0	0	5	15	5	37%
30	4811.59.10	Aseptic Pack Paper/ Aluminum Foil	10	0	0	5	15	5	37%
31	4811.59.90	Unprinted Paper for Ribbon Pack	5	0	0	5	15	5	31%
32	4822.90.00	Roll Stock Tyvek Paper	5	0	0	5	15	5	31%
33	4823.90.91	Paper Separator	5	0	0	5	15	5	31%
34	4823.90.99	Unprinted Wrapper Paper	5	0	0	5	15	5	31%
35	6804.10.00	Grinding Stone	10	0	0	5	15	5	37%
36	6804.22.00	Cutting Disk	5	0	0	5	15	5	31%
37	8481.40.12	Auto Safety Valve (Dia < 1 inch)	5	0	0	5	15	5	31%

Sl.	HS Code	Name of raw material	CD	RD	SD	AT	VAT	AIT	TTI
38	8481.40.12	Manual Safety Valve (Dia <1 inch)	25	3	0	5	15	5	59%
39	8481.80.22	Solenoid Valve	5	0	0	5	15	5	31%
40	8516.90.10	Heater Coil	5	0	0	5	15	5	31%
41	9018.39.17	Blood Lancet	10	0	0	5	15	5	37%
42	9018.39.90	Luer Needle with plastic protector	5	0	0	5	15	5	31%
43	9031.90.00	Parts of Burette Set	1	0	0	5	15	5	26%
44	9033.00.00	T -Connecter	10	0	0	5	15	5	37%
45	8309.90.90	Stoppers, caps and lids.	25	3	45	5	15	5	128%
46	8309.90.30	Combination seal for vials	25	3	0	5	15	5	59%
47	7214.99.00	Various Iron/steel bars and rods	5	3	45	5	15	2	90%

CD= Customs Duty, RD= Regulatory Duty, SD= Supplementary Duty, VAT= Value Added Tax, AIT= Advanced Income Tax, TTI= Total Tax Incidence

Bangladesh Investment Development Authority
BIDA

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