Medical Device Regulation in the European Union - Costs and Procedures: How the Government can Support Exporters

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Executive Summary

The European Union medical device regulation (EU MDR) is a set of rules that govern clinical research, medical device manufacturing, and distribution throughout Europe. As a result, the European surgical market has become one of the most regulated sectors in Europe, with the goal of minimizing human loss and ensuring that all items entering the market meet all health and safety standards. To further regulate the surgical sector, the European Parliament established new guidelines in 2017 for manufacturers and distributors from around the world wishing to access European markets. Prior to this, the MDD, or Medical Device Directive, was enforced, which had fewer regulatory measures and was less technical than the current MDR. From May 26th, 2024, all devices on the market must be in compliance with the regulation. Following that, any device that has not been registered under the new regulation will be barred from entering the European market. Under the new medical device rule, manufacturers must provide more specific clinical data to support their safety and performance claims.

This study presents a quick overview of the European medical device regulation act, which must be grasped before proceeding. The regulation document is made up of 134 articles and annexures to those articles. The report selects the relevant articles and annexures that are required in the registration process in order to assist Pakistan's exporters. Moreover, the registration process is split into simple and self-explanatory steps. The requirements and expenditures involved are briefly discussed at each step. The study also details fees for notified bodies, government registration fees, and other payments at each stage of the procedure. Manufacturers face significant challenges due to the high cost and technicality of documents. Pakistan’s surgical devices will lose a large portion of their export if they are not registered under this new scheme due to a lack of support. The study also examines the prospective costs and benefits of registration, which will not be restricted to monetary charges but will also consider the changing dynamics of the medical device industry.

1.Introduction

Medical devices and In Vitro Diagnostic medical devices (IVDs) have a fundamental role in saving lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease. The EU has a competitive and innovative medical devices sector, characterized by the active role of small and medium-sized enterprises. It is supported by a regulatory framework that aims to ensure the smooth functioning of the internal market, taking as a basis a high level of protection of health for patients and users.

There are over 500,000 types of medical devices and IVDs on the EU market[1]. Examples of medical devices are sticking plasters, contact lenses, X-ray machines, pacemakers, implants, software apps, and hip replacements. IVDs are used to perform tests on samples, and examples include HIV blood tests and blood sugar monitoring systems for diabetics.

The Medical Device Regulation (MDR), also known as the European Union Medical Device Regulation (EU MDR 2017/745), is a new set of regulations that control clinical research, manufacturing, and distribution of medical devices in Europe. Medical device businesses that want to sell their products in the European market must comply with this rule. From May 26th, 2024[2], all devices on the market must follow the regulations. Following that, any gadget that has not been registered under the new legislation will be barred from entering the European market. For commercial use, a Communaute Europeenne marking certificate is necessary, which validates that the medical equipment meets all of the standards listed in the guidelines.

The Medical Device Regulation will help improve the safety and performance of medical artificial intelligence devices entering the market. The Medical Device Regulation introduces new rules for risk classification of devices, which will result in more devices being subjected to a higher degree of scrutiny before entering the market; more stringent requirements on clinical evaluation, including the requirement for appraisal of clinical data; new requirements for post-market surveillance, which may help spot early on any new, unexpected side effects and risks of the

[1] https://ec.europa.eu/health/medical-devices-sector/overview_en
[2] https://www.networkpartners.com/resource/eu-mdrs-impact-class-reusable-instruments/

devices; and requirements for notified bodies, including for expertise of the personnel and consideration of relevant best practice documents.

According to the new regulations, medical devices are classified into three classes and six subclasses. Class I devices are all non-invasive devices. Non-invasive liquid storage devices are classified as class II, while surgical invasive systems are classified as class III[3]. Pakistan's normal exports to the European Union fall under Class 1, which is reusable surgical products, according to EU MDR 2017/745.These instruments are classified as "MDS-1006" surgical devices[4].

The E.U has long been the largest export destination with annual total sales of medical devices worth approximately 180 billion[5] with a total population of more than 447 million[6], while Pakistan's share in this market worth billions is only USD 160 million[7], which makes only 0.008% of the market share that these exports are concentrated to a few top exporters. Most of the products exported by Pakistani manufacturers are conventional surgical goods. This export share can be reduced or can be completely contracted due to the changing and evolving techniques that are being used in surgeries. The field is actively evolving and new innovations are being made to minimize the involvement of human beings or with minimal use of instruments which are directly operated by humans. The sole purpose of these innovations is to minimize human involvement in the process. These innovations will help to reduce human errors in surgical processes.

Compliance with the regulation requires a hefty investment and numerous technical documents, which are hard to manage without specialized supervision. The registration process has been completely overhauled compared to the previous registration process due to the numerous technical factors that are involved while determining the cost and completing the technical documentation. The study is going to identify the factors that are directly and indirectly related to the registration process. Manufacturers usually require support in such new ventures from the government. Furthermore, the government must provide technical assistance to manufacturers;

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
[4] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
[5] https://www.medtecheurope.org/wp-content/uploads/2021/06/medtech-europe-facts-and-figures-2021.pdf
[6] https://ec.europa.eu/eurostat/cache/digpub/demography/bloc-1a.html?lang=en
[7]https://www.trademap.org/Country_SelProductCountry_TS.aspx?nvpm=1%7c586%7c%7c%7c%7c901890%7c%7c%7c6%7c1%7c1%7c2%7c2%7c1%7c2%7c1%7c1%7c1

otherwise, more than USD 160 million in business would be lost, and Pakistan would be unable to acquire any future business.

1.1 Historical regulations of European Union related to Surgical goods

Prior to the Medical Device Regulation Act, the Medical Device Directive (MDD)[8] and the Active Implantable Medical Devices Directive (AIMD)[9] [2] were enforced in the European Union for more than 20 years. According to the medical device directives, the regulation was enforced upon the national bodies, while in MDR the regulation is to be complied with by the manufacturers and the exporters[10].

The procedure to get registered for MDR and MDD was processed through notified bodies, but MDR is costly and very technical in comparison to the earlier regulation. The sole purpose of excessive technicality and documentation is to minimize the costs that are associated with faulty surgical equipment and human involvement.

[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01993L0042-20071011
[9] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01990L0385-20071011
[10] European Commission, DG Health and Consumers, "Guideline for Authorized Representatives," January 2012

2.Steps for Manufacturers/Exporters to be MDR compliant

Medical device regulation is a vigorous and hefty process. Numerous manufacturers and exporters are finding it difficult to complete the registration process as per the new regulations. The main reason for this is the excessive technical documentation involved in the process. (Links to mentioned articles and annexure are attached at the end of the report.)

Step 1: Check and confirm that the product is a medical device.

a. Medical devices as defined in MDD
b. Article 2(1) describes the properties of medical devices[11].

Step 2: Confirm that the product is a Class I medical device.

a. Classification according to Annexure VIII of EU MDR 2017/745[12].
b. Reusable devices

Step 3: Procedures and technical documentation preparation

a. Meeting general safety and performance requirements for the device as mentioned in Annexure I of EU MDR 2017/745[13].
b. Clinical evaluation of the product, which is an important step in MDR, which is mentioned in MDCG
c. Clinical evaluation and documentation in accordance with Article 61 and Part A of Annex XIV
d. Preparation of technical documentation.
    i. Justification for Classification
    ii. In the documents, references to the predecessor and similar devices are made.

[11] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
[12] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
[13] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745

iii. Establishment of UDI (Unique Device Identification)- Defined in MDCG 2018-1 V2[14].

Step 4: Request for Notified Body Involvement

a. Reusable Surgical Instruments Code "MDS 1006"
b. The NANDO database can be used as the list of notified bodies—a new approach to notifying and designating organizations[15].
c. There is a total of 20 notified bodies listed in the NANDO database[16].
d. Article 52(7) of EU MDR 2017/745 addresses the role of notified bodies in the use of Class 1 reusable surgical instruments.

Step 5: Create product instructions and labeling[17].

a. Annex I contain usage instructions.
b. Language requirements and distributor information
c. Requirements are mentioned in Annex I, Chapter III (23) and Article 7.

Step 6: Verification of compliance with general manufacturer obligations

a. Establishment of QMS and Insurance as mentioned in Article 15[18].
b. EN 46000-European standard for quality systems specific to medical manufacturers[19].

Step 7: Draw up the EU Declaration of Conformity[20].

a. Declaration as per the terms mentioned in Annex IV
b. Device name registered trademark unique reference

[14] https://ec.europa.eu/health/system/files/2021-04/md_mdcg_2018-1_guidance_udi-di_en_0.pdf
[15] https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34
[16]https://www.emergobyul.com/blog/2021/05/20th-notified-body-designated-under-eu-mdr-while-ivdr-designations-lag
[17] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
[18] https://www.mantrasystems.co.uk/eu-mdr-compliance/quality-management-system-qms
[19] https://www.qualitydigest.com/mar99/html/body_standard.html
[20] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745

c. Device's intended use
d. Classification of device risk
e. Information about the manufacturer

Step 8: Apply the CE (Communauté européenne) label.

a. CE marking along with the identification number of notified bodies.

Step 9: Device and manufacturing registration in EUDAMED

a. Manufacturers must register themselves with EUDAMED.
b. SRN (serial number) is assigned to each manufacturer.
c. After registration, products are assigned UDI-DI**.**

2.1 Associated costs at each step for Medical device regulation

Sr No.	Cost Description at each step	Cost in USD
1	European Representative fee on Step 2	$950
2	UDI Setup-To be paid on Step 3	$1,000
3	Notified body fee on Step 4	$22-25,000*
4	Representation fee on Step 7	$9,000
5	Cost of Annual follow up/Audits	$5,000
6	CE marking and certification on Step 8	$15-30,000**

*The CE marking fee for small manufacturers with fewer than 30 employees are $13,000[21].

*The CE marking fee for firms with employees from 30 to 100 is $17-19,000[22].

[21] ttps://www.dqs-med.com/good-to-know/certification-documents
[22]https://www.mddionline.com/news/exportinggetting-small-device-companies-through-ce-marking-maze#footnote

*The cost varies depending on the notified body; there are a total of 20 notified bodies. Body is considered based on the type of surgical goods manufactured by the company[23].
**Fee depends on size and volume of manufacturing and production.

3.Pakistan's Surgical sector exports

Pakistan's surgical exports were valued at USD 420.93 million[24] in the year 2021, while the total surgical exports in the year 2020 were approximately USD 362.34 million[25]. The annual increase in surgical exports was 13.9%[26] during the years 2020–2021.

Table 1:Pakistan's Surgical exports

Code	Product label	Exported value in 2021 ($ Million)
'901890	Instruments and appliances used in medical, surgical or veterinary sciences, n.e.s.	416.79
'901839	Needles, catheters, cannulae and the like, used in medical, surgical, dental or veterinary **...**	3.06
'901849	Instruments and appliances used in dental sciences, n.e.s.	0.68
'901819	Electro-diagnostic apparatus, incl. apparatus for functional exploratory examination or for **...**	0.24

Source: ITC, Trade Map

[23] https://www.dqs-med.com/good-to-know/mdr-preisliste
[24] Trade Map
[25] Trade Map
[26] The author's calculation

3.1 Pakistan's Surgical exports to European Union

Pakistan's surgical exports to the European Union were valued at USD 120.04 million[27] in the year 2021, while this value in the year 2020 was around USD 105 million[28]. Germany was the top trading partner in Europe with the highest export value in the year 2021. Exports to Germany alone amounted to 54 million out of 120.04 million, accounting for more than 48% of Pakistan's total surgical exports to the European market[29].

Table 2:Pakistan's Top trading partner in European Union

Country	Exported value in 2021 USD Millions
Germany	54
France	12.5
Italy	7.4
Netherland	6.5
Belgium	4.5

Source: ITC, Trade Map

Germany's total imports from the world of surgical equipment were valued at USD 4.33 billion[30] in the year 2021, making it the second largest importer of surgical equipment. Pakistan's exports of cannulas and needles H.S code 9018.3900 increased from USD 1000 in 2020 to USD 2.93 million in 2021[31] due to increased demand for this equipment and decreased domestic production in the European market. The second major increase in Pakistan's exports in the sector was of

[27] UNCTAD
[28] UNCTAD
[29] Pakistan Customs, Weboc

[30] Trade Map
[31] Trade Map

electrodiagnostic apparatus, H.S code 9018.9010, from USD 38000 to USD 191 million in the year 2021.

3.2 Pakistan Surgical goods industry

The total number of surgical exporters registered in Pakistan is 1715[32]. Out of these, major export shares are concentrated on a few large-scale manufacturers. 190 million out of a total of 420 million is only exported by 59 large-scale manufacturers, which is around 45% of export share with 3.44% of the total number of firms[33].

Table 3: Pakistan's Surgical Sector

Size	Exported value in 2021 USD Millions
Large Scale Exporters	190
Medium Exporters	140
Small scale	90

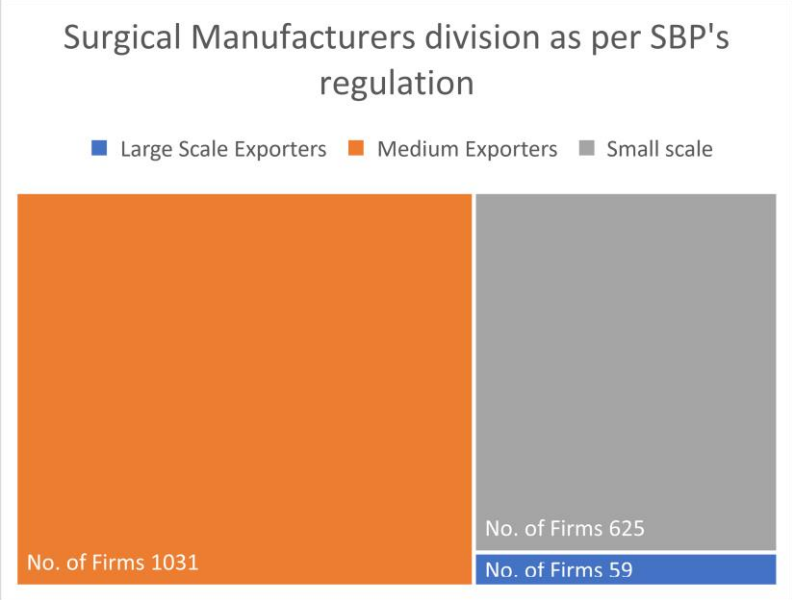
Source: PRAL, Customs

Out of a total of 1715 active exporters of surgical sectors, 59 firms are large-scale exporters, while the number of medium and small-scale exporters is 625 and 1031, respectively. Most firms fall into the category of small exporters due to their export market share. The major reason for only a few firms falling into the category of large-scale exporters is due to complex requirements to export products to high-end markets, which make it difficult for the smaller firms to participate in

[32] https://simap.org.pk/
[33] PRAL

markets which have high surgical good demand. The classification of the firms is based on the factors provided by the State Bank of Pakistan's regulations.

Figure 1: Tree Map: Number of Firms with Market share in Pakistan



Source: PRAL, Pakistan Customs

4.Sectoral costs and benefits associated with MDR

The major surgical export share is concentrated on a few large-scale manufacturers. These firms are major exporters of surgical items to the European market. Firms with the top export share in the European market are already CE marked. Surgicrafts, QSA Surgical, and Frigz International are the top 4 exporting firms in the surgical sector with a market share of PKR 1.46Bn, 1.419Bn, 1.35Bn, and 1.079Bn respectively. These four firms are already CE marked and are in the implementation process of a quality management system to get registered under the medical device regulation.

MDR, as discussed above, was introduced to import surgical products with minimum human involvement, which can reduce human error. MDR's main focus is on attracting and importing AI enabled devices which can revolutionize the European surgical sector. Due to the changing dynamics of the surgical sector, most developed countries are upgrading conventional surgical techniques to electronic surgeries. Frigz International is the only large-scale manufacturer exporting products to the European market which are used in electronic surgeries; instruments like electrodes, forceps with cables, speculums, etc. Although these products are also just used as helping instruments in modern surgeries rather than devices as a whole, which can be used to perform the whole surgical process.

Pakistan's surgical sector is still suffering from coping with the changing dynamics of the global surgical industry. Pakistan still specializes in conventional surgical products and their market share is diminishing in developed countries. The import share of conventional surgical products by the developed countries has decreased by almost 45% over the last 5 years. Al-enabled and electronic products with high precision and minimum incision are taking over the surgical sector, which is an alarming situation for Pakistan. Pakistan's main exports remain products related to traditional surgical procedures.

Major products exported by Pakistan include Laryngoscopes, Otoscopes, hammers, proctology, different scissors used in ENT and dental surgeries, and forceps used for endoscopic surgeries, which are decreasing over the course of time even in Pakistan. Increasing exports is one, but due to these changing trends, Pakistan has to import infrastructure for these new surgical processes, which is increasing Pakistan's import bill. Extensive research and development is required in this sector to not only increase Pakistan's exports but to also control its import bill.

This transition from the old system to the new one is likely to raise costs for Pakistani manufacturers and distributors that are operating in the European market. Moreover, the heightened regulatory scrutiny and likely reduction in the number of credentialed notified bodies that were available for the MDD registration may eliminate Pakistan's market share in the European market for small and medium-sized manufacturers and distributors. Although the market share of small and medium manufacturers is already very low and major exports are carried out by large-scale manufacturers, on the basis of the above factors, the question arises whether it is feasible for all the manufacturers to get registered as per medical device regulation. The costs associated with this regulation are way greater than the export earnings. The payments transferred are also going to affect the exchange rate in the global market due to increased supply.

Start-ups and SMEs in manufacturing sectors often do not have sufficient funding to provide extended clinical evidence or to conduct clinical trials. This barrier is not only because of the funds

but also due to technicalities involved in the process. This may eventually reduce Pakistani manufacturers' export share in European markets, both small and large-scale. There is no clarity on the requirements, and the regulatory burden on the manufacturers has increased. Notified bodies in the European union and their sub offices are unable to give advice, which leaves the manufacturers with no clear route for consultations.

European medical device regulation has made obligations to manufacturers to track medical devices already on the European market as well as for post-market surveillance. This type of regulation will create higher costs for the life cycle of each individual medical device, which is not only going to be difficult for the small and medium-scale manufacturers but for the large-scale manufacturers and distributors as well. Such increased costs are also going to be a factor which is going to limit the expansion and creation of other devices. Considering this factor for a country like Pakistan, which is already suffering in the research and development budgets, such costs are going to further decrease the innovations in this sector, which is going to diminish the market share of Pakistan's surgical products not only in Europe but around the globe. A survey from the Regulatory Affairs Professionals Society and KPMG concluded that only about one-quarter of medical device firms are prepared to fully comply with the MDR, and more than one-third of respondents indicated that they would spend more than $5 million to become MDR compliant[34].

The above factors should be kept in mind while formulating a policy for the new medical device regulation and the European markets, not only by the manufacturers and distributors but by the government authorities as well.

4.1 Consequences for Government Regulatory bodies

Higher standards and new layers of regulatory oversight will add strain to the capacity of competent authorities, creating the potential for delays throughout the regulatory

[34] Medical Design and Outsourcing, "Report: Most Medical Device Makers Not Ready," September 24, 2019. The survey generated responses from 230 firms, mostly in the EU and North America.

approval, market surveillance, and recall stages of the medical device life cycle. One industry assessment highlighted the heavier demands on these authorities, both from the increase in the number of medical devices and the expanded definition of a medical device. These new demands have increased the strain on government regulatory bodies.

5.Recommendation and Gap Analysis

1- Clarification of the process for entrepreneurs. The main purpose of MDR was to allow artificially intelligent surgical products to enter the European markets, which requires innovations in the process which are usually developed by entrepreneurs and innovators[35]. MDR is not clearly defined for entrepreneurs and individuals and is costly, which can halt the process of innovation and new inventions.

2- Surgical associations should make assessments of the effects that the enforcement of the MDR will have on manufacturers and distributors. Moreover, is it actually feasible for the manufacturers to get registered as per the costs involved and mere export share in a billion-dollar market?

3- Campaigns to raise awareness and educate the public about the MDR and its requirements

[35]https://ec.europa.eu/health/medical-devices-sector/directives_en

4- Using this shift to promote education and research on regulatory science and health technology is a great idea.

5- Creating funding mechanisms to help start-ups offset the costs associated with becoming compliant.

6- Support in the form of subsidies should be provided to small and medium-sized manufacturers who have the potential to grow in the European market because the cost and technicality involved in the registration process are hard to meet by small-scale manufacturers.

7- As discussed in the report, the dynamics of the European surgical market are changing. Demand for conventional surgical equipment has decreased drastically. Pakistan, in the current scenario, cannot cope with this technological advancement without extensive research and development in this sector. New markets should be explored for exports of surgical equipment.

8- Pakistan's manufacturers and distributors should primarily focus on new potential African and Middle Eastern markets to increase their export share of surgical equipment. Africa's total import of surgical equipment is USD 2.44 billion[36], out of which approximately USD 1.35 billion[37] of imports are of conventional surgical equipment, which makes up around 55.4% of total imports, while Pakistan's export market is only USD 15.5 million[38]. (These are the same surgical equipment in which Pakistan's manufacturers have a production advantage.

[36] UNCTAD
[37] UNCTAD
[38] UNCTAD

6.Conclusion

The overall goal of the medical device regulation passed by the European Union parliament was to increase the quality and safety standards of medical devices. However, due to the increased requirements in the new regulations, some products which are being exported from developed nations like Pakistan might cease to exist in the European markets due to extensive and technical scrutiny as discussed in the report.

The communication barrier with the stakeholders involved is one of the prime challenges in the implementation of this regulation to world-wide manufacturers. This is one of the reasons that the registration date is being extended from time to time. Most of the staff of notified bodies lack training and information in this regard, which is the only help available for the manufacturers and distributors. In this regard, a successful, smooth regulatory process and greater collaboration will be beneficial.

However, in the context of Pakistan's surgical sector and the shift in demand in the European market due to technological advancement, spending funds and subsidies on such a program is not beneficial for the government, keeping in question the points discussed in the analysis. Moreover, if at any part, the government wants to intervene, it should be in the research and development of the surgical sector as it lacks even the basic use of technology in production, which can in the near future affect the export share in the European market but in many other different markets as well. This lack of technological advancement can affect export share on one hand, but can also increase Pakistan's import bill due to domestic demand.

African and Middle Eastern markets are yet to be explored, with adequate potential for Pakistan to grow its market share. As it is currently as per the MDR regulations and European markets, it is hard for Pakistan's manufacturers and distributors to increase their export share in the European Union and should not be considered as a fixed destination. Exporters and manufacturers have to

work on research and development of the sector and adapt to a continually evolving pathway which can increase the export share in the European market.

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Annexures

Link for Articles and Annexures mentioned in the steps for reference:

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