

Embassy of Pakistan
Commercial Section
Brussels (Belgium)

25th February, 2019

Subject: - PRODUCT REPORT ON SURGICAL INSTRUMENTS

Respected Sir,

Kindly refer to the subject cited above.

2. Please find enclosed Product Report on Surgical Instruments, prepared by Commercial Section Brussels.

Regards,

Salman Ah
(Salman Ahmed Choudri)
Commercial Secretary

Encl: (As Above)

Secretary
Trade Development Authority of Pakistan
Karachi

TO the concerned
RA.

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Muhammad Saad Ahmed Faruqi
Secretary
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Mr. AFSHAN
UROOS
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Copy for information to:-

- i. Deputy Secretary (Europe), Ministry of Commerce, Islamabad.
- ii. P.A to Ambassador of Pakistan, Belgium, EU & Luxembourg.

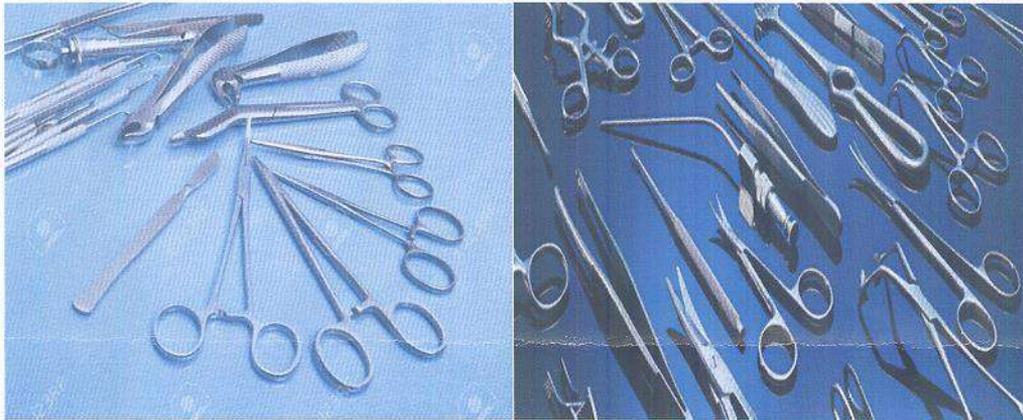
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“Surgical Instruments” (Product Report)



Commercial Section
Embassy of Pakistan, Brussels

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1. Definition and Product Description:

Surgical Instruments are tools or devices that perform such functions as cutting, dissecting, grasping, holding, retracting, or suturing. Surgical instruments facilitate a variety of procedures and operations. Rising prevalence of chronic diseases such as neurological, cardiovascular, urological, and other disorders is creating immense burden on the global health of the society.

Such increasing burden has led to the development of therapies and treatments, thereby leading to rising demand for surgical instruments. This increased demand is mainly concentrated in North America and Europe, which is mostly driven by their aging population base and growing tourism. The instruments and appliances used in medical, surgical, dental or veterinary are classified under Chapter 90 of the HS codes.

Table 1

HS Code / Product	HS Code (6 Digits)
9018 / Instruments and Appliances uses in Medical, Surgical, Dental or Veterinary Sciences	901811- Electro Cardiographs
	901812- Ultrasonic Scanning apparatus
	901813- Magnetic imaging apparatus
	901814- Scintigraphic apparatus
	901819- Electro diagnostic apparatus
	901820- Ultraviolet or Infrared apparatus
	901831- Syringes
	901832- Tubular metal needles
	901839- Needles, Catheters, Cannulae
	901841- Dental drill engines
	901849- Instruments used in dental
	901850- Ophthalmic instruments and appl
	901890- Instruments used in medical, surgical or veterinary sciences

2. Europe's Imports of Surgical Instruments:

Europe is one of the largest markets for imports of surgical instruments from the world. The total import of surgical instruments by EU in 2017 was worth **16.25 Billion EUR** which was 1.08% higher than imports in 2016. According to estimates, the demand market will continue to grow with increasing demand for safe, cost and time-effective solutions.

Table 2

Imports of Surgical Instruments from EU extra		
Sr.No	Country / Partner	Imports (2017) (In Million Euros)
1.	United States	7,240.39
2.	Mexico	1,636.73
3.	China	1,451.72
4.	Japan	1,149.05
5.	Costa Rica	468.38
6.	Malaysia	391.05
7.	Israel	337.38
8.	Singapore	312.63
9.	South Korea	287.64
10.	Taiwan	188.92
<i>Source: Eurostat</i>		

The European market is dominated by United States with a share of 44% in the import of surgical instruments followed by Mexico (10%), China (9%), Japan (7%), Costa Rica (3%), Malaysia (2%), Israel (2%), Singapore (2%), South Korea (1%) and Taiwan (1%). Together these top ten countries make up for 80% of the import market in the EU.

Among the developing countries, Mexico and China are the leading suppliers of surgical instruments to EU. However, other developing countries have also seen increase in their annual export rates such as Costa Rica (22%), Malaysia (5%), Vietnam (29%), India (19%) and Thailand (16%). These statistics clearly show that

there exists immense potential for developing countries in the surgical sector with increased value addition, branding and better pricing.

3. Pakistan's Exports to Europe:

Pakistan has a well-established surgical instruments industry which is not only catering to the domestic market but also generating foreign exchange earnings. According to estimates, over 90% of total production is exported to the US, Europe, Latin America and other markets.

Despite having the raw materials, skilled labour force and competencies, the surgical industry of Pakistan has not been able to fully capitalise on the potential of its exports. Pakistan exported surgical instruments worth 105.92 Million EUR in 2017 which is not even 1% of the total market share.

Table 3

Direction of Pakistan's Exports to EU in 2017		
Country/ Partner	Exports Volume (In Million Euros)	% Share
Germany	38.47	36%
United Kingdom	28.64	27%
France	10.0	9%
Belgium	3.78	4%
Netherlands	2.09	2%

Pakistan's major export destinations are Germany, UK, France, Belgium and Netherlands. Together these countries make up for 78% of Pakistan's total exports of surgical instruments to Europe. Pakistan's ranking in the top five EU countries are as under:

- Germany: Pakistan is ranked 10th in surgical instruments imports;
- United Kingdom: Pakistan is ranked 5th in surgical instruments imports;
- France: Pakistan is ranked 12th in surgical instruments imports;
- Belgium: Pakistan is ranked 19th in surgical instruments imports;
- Netherlands: Pakistan is ranked 20th in surgical instruments imports;

Pakistan's major competitors in the EU market are US, China, Mexico, Japan, Costa Rica, Malaysia, Vietnam, Singapore, Taiwan and South Korea.

4. Belgium's Import Market for Surgical Instruments:

Belgium is one of the leading importers of surgical instruments from the world because the country is a trading hub for companies associated with the surgical sector within Europe and outside. Belgium's total imports of surgical instruments in 2017 were worth 4.99 Billion EUR. Out of these, **2.6 Billion EUR** worth products were imported from outside Europe.

Table 4

Top Exporter for Surgical Instruments in the Belgian Market				
Ranking	Country / Partner	Exports (2016) (In Million Euros)	Exports (2017) (In Million Euros)	% change
1 st	United States	1,277.0	1,313.74	2.8%
2 nd	Luxembourg	838.66	742.97	-11.4%
3 rd	United Kingdom	314.23	343.24	9.2%
4 th	Germany	341.74	320.03	-6.3%
5 th	Netherlands	248.56	298.15	19.9%
6 th	Mexico	362.99	271.72	-25.1%
7 th	Costa Rica	197.68	230.35	16.5%
8 th	Japan	193.45	186.16	-3.7%
9 th	Ireland	164.16	163.85	-0.19%
10 th	France	152.94	149.87	-2.0%

Source: Eurostat

Belgium's import of surgical instruments increased by 3.3% in 2017 as compared to imports during the same period last year. Among the developing countries, many have seen an increase in their annual export rates such as Costa Rica (16.5%), Vietnam (53.5%) and India (47.05%).

5. Pakistan's Competitors in the Belgian market:

Pakistan faces a stiff competition in the Belgian market despite having all the resources, economies of scale, skilled labour force and wide product range. The major reasons are as under:

- ✓ Lack of marketing and distribution - the industry is mostly SMEs; therefore they do not have the resources to market their products on their own. Resultantly, they operate through international distributors and traders.
- ✓ No branding - Unlike competitors such as China, India, Vietnam, Pakistan's surgical industry has no established brands. Most products get exported to other countries, where they are branded and sold in the international market at high prices.
- ✓ Technology Constraints - Pakistan's surgical industry lacks R&D for developing new sophisticated products for niche markets like Europe and America.

Table 5

Pakistan's Competitors from EU Extra Countries		
Rank	Country / Partner	Exports (In Million Euros)
16 th	China	68.92
17 th	Vietnam	49.81
19 th	Malaysia	34.23
29 th	Philippines	10.1
30 th	India	9.85
36 th	Pakistan	3.78

Source: Eurostat

During the period January – November 2018, Belgium imported surgical goods worth 4.24 Billion EUR and Pakistan exported products worth 3.14 Million EUR. This clearly shows that there exists a lot of export potential for Pakistan in the Belgian market through diversification, R&D, compliance to EU requirements and branding.

6. Regulations / Requirements for Import of Surgical Instruments

European Union has in place certain specific requirements for the import of surgical instruments. Some of the most relevant are as under:

Medical Devices Directive 93/42/ECC: This pertains to quality and labelling requirements:

Quality – EU markets require CE marking. The requirements include a quality system for design, manufacture, and final product inspection and testing (such as ISO 13485).

Labelling – the label, the outer packaging and instructions for use must contain the name and address of the authorised representative if the manufacturer does not have a registered place of business in the EU. It must also have information essential to identify the device and the contents of the packaging, especially for the end users.

- ✓ The product must include the word STERILE (where appropriate),
- ✓ the batch code preceded by the word LOT or the serial number;
- ✓ where appropriate, the date by which the device should be used, in safety, expressed as year and month;
- ✓ where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the European Union;
- ✓ if the device is custom-made, the phrase "custom-made device";
- ✓ if the device is for clinical investigations, the phrase "exclusively for clinical investigations";
- ✓ any special storage and/or handling requirements;
- ✓ any special instructions for use;
- ✓ any warnings and/or precautions to be taken;
- ✓ year of manufacture for active devices other than those covered under (e). This indication may be included in the batch or serial number;
- ✓ where applicable, method of sterilisation.

EN868 & ISO 11607: These pertain to the packaging of medical devices. Part 1 of EN868 relates to medical devices require sterile packaging. Part 2 to Part 10 relate to the requirements and test procedures for the packaging materials. These tests can be used to show that all requirements have been complied with.

ISO 11607 (Part 1) is on the requirements and test procedures for packaging materials, and Part 2 on the validation requirements of packaging processes. While EN868 is mandatory, ISO is a voluntary standard and is often requested by customers.

European Packaging and packaging waste legislation: This legislation restricts the use of certain heavy metals and states other requirements. The EU also has requirements for Wood packaging materials used for transport, such as packing cases, boxes, crates, drums, pallets, box pallets and dunnage.

Additional requirements:

- ✓ Complying with voluntary standards, such as IEC/EN 60601, could help you obtain CE marking for your product.
- ✓ Other voluntary standards address organisational (such as ISO 13485), environmental and social/labour requirements.
- ✓ Governments, industries and consumers are increasingly aware of sustainability issues. The Eco design Directive 2009/125/EC helps to improve the energy efficiency of products and is complemented by the Energy Labelling Directive for labelling requirements.

7. Challenges to Pakistani Exporters:

The major challenges to the surgical industry and exporters are as under:

- a. Pakistani exporters are facing stiff competition from countries like China, Mexico etc due to cheap labour and technological innovation.
- b. Europe has in place strict quality requirements for surgical instruments being imported from the world. Industry associated with the surgical sector especially SMEs do not have ISO and Current Good Manufacturing Practices (CGMPs) Certifications to allow their products market access to the Europe.

- c. Unlike our competitors, Pakistan has no renowned brands in the international market. Resultantly, the buyers for Pakistani products are mostly distributors and wholesale dealers who sell these products under their own brand names. Also companies do not have the resources to establish their own distribution networks in the European markets.
- d. Lack of technological advancement restricts Pakistan's potential in terms of exports. Pakistani exporters are still manufacturing traditional products. There is a huge market for production of instruments through other materials such as plastics and synthetics.

8. Recommendations:

The following recommendations are made:

- a. Exporters need to comply with the regulations and requirements of the European Union. There is a need to sensitise the exporters about the EU requirements such as ISO Certifications, Medical Devices Directives pertaining to quality and labelling etc. Ministry and TDAP may consider organising seminars with the support of Sialkot Chamber and SIMAP to sensitise the surgical industry especially the small firm.
- b. A delegation of surgical instruments exporters should be arranged to visit Belgium. This office will arrange their meetings with major importers / wholesale dealers and distributors. This would help the industry in understanding the requirements of the European markets and can help them establish direct linkages with the importers.
- c. Through public-private partnership, the surgical industry must focus on research and development, which can help in adapting to new methods of production but also develop new products that are made out of plastics and synthetic material.

9. List of Major Belgian Companies associated with Surgical Instruments

Sector:

Etablissements Van Houdt BVBA

+32 32379961

www.vanhoudt-medical.be

Van Hopplynus Instruments SA

+32 22292929

info@vanhopplynus.com

Instrumentation Difra SA

+32 87898080

info@difra.be

www.difra.be

Societe Auxiliaire De Distri D'art Medicaux SPRL

+32 25116339

www.fremineurbandagistesbruxelles.be

Medtronic Belgium NV

+32 24560900

reception.brussels@medtronic.com

www.medtronic.be

Mathys Orthopaedics Belux NV

+32 16388120

www.mathysmedical.com

Stöpler Belgium NV

+32 22673810

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www.stopler.be

Surgical Instruments Belgium SA

+32 81450459

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www.sibel.be

Carl Zeiss NV

+32 27193911

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www.zeiss.be

Hospithera SA

+32 25350202

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Maquet Netherlands Bv VBR
+32 32320014
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Belgian Diagnostic Company SA
+32 84313780
info@beldico.be
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Silvert Medical NV
+32 23962524
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Disposable Medical Equipment SA
+32 65673754
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Wm Supplies (B) BVBA
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Terumo Europe NV
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Eppendorf Application Technologies SA

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Maison Luc Medical SPRL

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Matton Orthopedie NV

+32 92233114
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www.orthomatton.com

Centre Wallon D'orthopedie Generale SCRL

+32 71468151
www.qualias-ko.be

Orthotaal

+32 51230877
info@orthotaal.be
www.quasta.be

D.s. Orthopedie

info@dsorthopedie.be
www.dsorthopedie.be

Permobil

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Medex Loncin

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10. Surgical Sector Associations:

Belgian Federation of Medical Technologies (beMedTech)

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0032 (0) 22570590
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**European Federation of Precision Mechanical and Optical Industries
(EUROM)**

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11. References:

- Eurostat, European Commission
- Pakistan Bureau of Statistics
- Surgical Instruments Manufacturers Association of Pakistan
- Kompass
