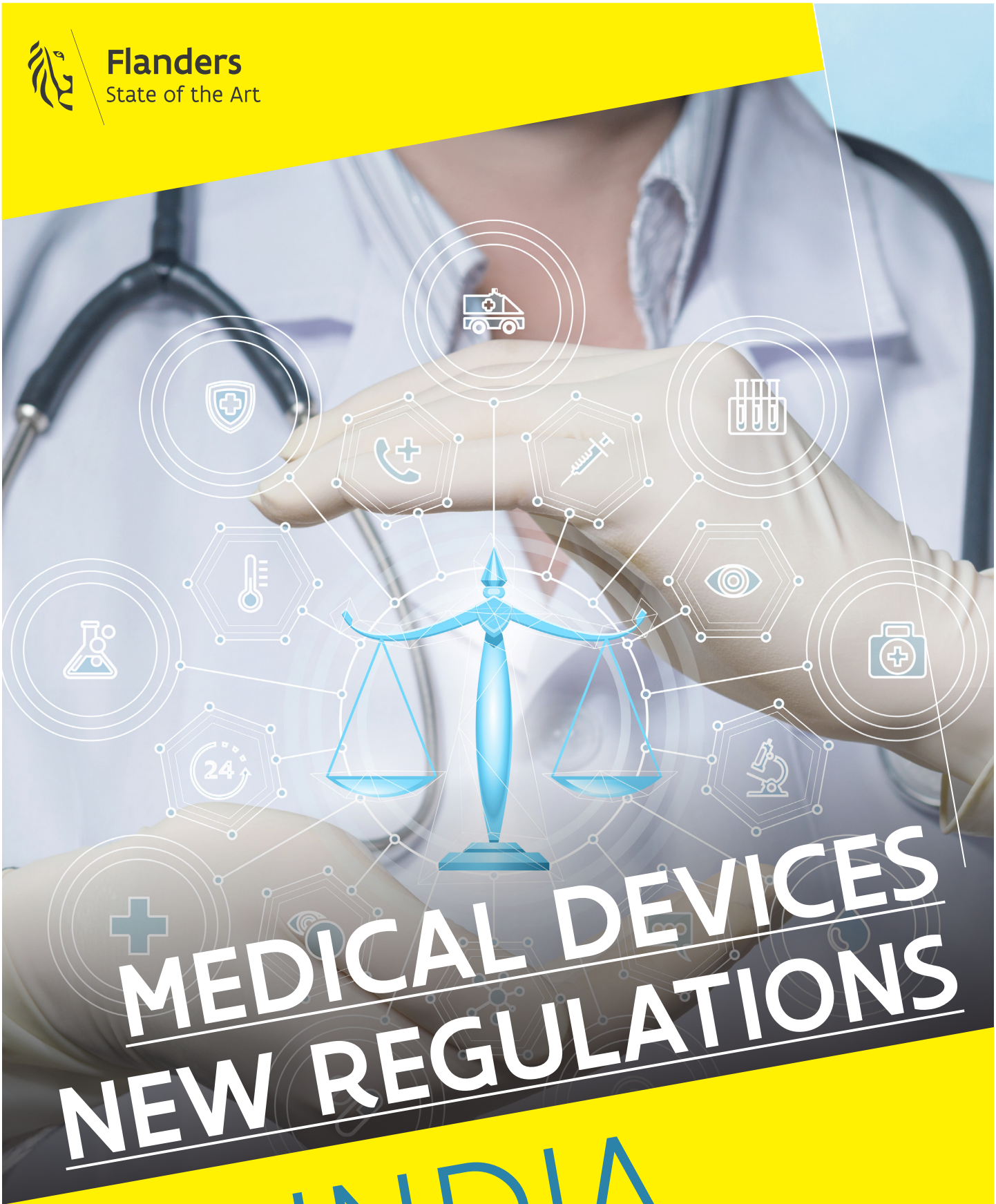
Flanders
State of the Art



MEDICAL DEVICES NEW REGULATIONS IN INDIA

FLANDERS INVESTMENT & TRADE MARKET SURVEY

FLANDERS
INVESTMENT &
TRADE

Market Study

MEDICAL DEVICES REGULATIONS AND PROCEDURES

The purpose of this document is to explain to the Flemish exporters of medical devices, the required registration and licensing procedures, when entering the Indian market. The regulation has been extended to all medical devices since 2020.

Publication date: 16.11.2021

Babette Desfossez
Trade & Investment Commissioner
Flanders Investment & Trade, New Delhi
Tel.: +91 11 42 428 100 - Email : newdelhi@fitagency.com

TABLE OF CONTENTS

1. INTRODUCTION

In India, the Central Drugs Standard Control Organization (CDSCO) oversees all regulations and registration of drugs, cosmetics, clinical trials, in vitro diagnostics and medical devices.
Before medical devices can be sold on the Indian market, they need to be compliant with the Indian medical devices regulations. The regulatory framework for medical devices is based on the Medical Device Rules 2017. Only the notified devices, which are a limited number of medical devices (37 categories) required registration in India.
On 01/04/2020, the Medical Device Rules, that regulates the "quality and safety of medical devices" was amended. The status of a medical device expanded beyond the 37 previously notified medical devices, requiring that all medical devices be registered under The Drugs and Cosmetics Act of 1940.
A medical device has been defined by the Indian authorities as follows[1]:

> All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of —
>
> (i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
>
> (ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
>
> (iii) investigation, replacement or modification or support of the anatomy or of a physiological process;
>
> (iv) supporting or sustaining life;
>
> (v) disinfection of medical devices; and
>
> (vi) control of conception.

On one hand, there are the notified devices, 37 categories of medical devices, which have been regulated since 2017 and on the other hand there are 24 new categories which have to be registered/licensed, which are referred to as non-notified devices.

2. NOTIFIED DEVICES (SINCE 2017)

Prior to the amendment, **only 37 categories of medical devices** were regulated.
The online registration process takes 1 to 2 years. A list of approved devices is published by CDSCO.

S. No.	Name of the Device
1	Disposable Hypodermic Syringes
2	Disposable Hypodermic Needles
3	Disposable Perfusion Sets
4	Substances used for in vitro diagnosis including Blood Grouping Sera
5	Cardiac Stents
6	Drug Eluting Stents

[1] Gazetted Publication

7	Catheters
8	Intra Ocular Lenses
9	I.V. Cannulae
10	Bone Cements
11	Heart Valves
12	Scalp Vein Set
13	Orthopedic Implants
14	Internal Prosthetic Replacements
15	Ablation Devices
16	Ligatures, Sutures and Staplers
17	Intra Uterine Devices (Cu-T)
18	Condoms
19	Tubal Rings 20
20	Surgical Dressings
21	Umbilical tapes
22	Blood/Blood Component Bags
23	Organ Preservative Solution*
24	Nebulizer (effective from 1 Jan.2021)
25	Blood Pressure Monitoring Device(effective from 1 Jan.2021)
26	Glucometer (effective from 1 Jan.2021)
27	Digital Thermometer (effective from 1 Jan.2021)
28	All implantable medical devices Equipment (effective from 1, April,2021)
29	CT Scan Equipment (effective from 1, April,2021)
30	MRI Equipment (effective from 1, April,2021)
31	Defibrillators (effective from 1, April,2021)
32	PET Equipment(effective from 1, April,2021)
33	X-Ray Machine (effective from 1, April,2021)
34	Dialysis Machine (effective from 1, April,2021)
35	Bone marrow cell separator (effective from 1, April,2021)
36	Disinfectants and insecticide specified in Medical Devices Rules, 2017
37	Ultrasound equipment (effective from 1, November, 2020)

3. NON-NOTIFIED PRODUCTS (SINDE 01/04/2020)

3.1 CATEGORIES

All medical devices, except for the notified devices (37 categories already regulated before 01/04/2020), are called non-notified products. They are divided into 24 categories.
Each device within the categories is classified as low risk (A class), low-medium risk (Class B), medium-high risk (class C) or high risk (class D). The risk classification is important for the deadlines regarding registration and licensing

1. Classification of Medical Device pertaining to Neurological under the provisions of Medical Devices Rules, 2017: 110 devices

2. Classification of Medical Device pertaining to Gastroenterology under the provisions of Medical Devices Rules, 2017: 153 devices

3. Classification of Medical Device pertaining to Oncology under the provisions of Medical Devices Rules, 2017: 48 devices

4. Classification of Medical Device pertaining to Pain Management under the provisions of Medical Devices Rules 2017: 26 devices

5. Classification of Medical Device pertaining to Software under the provisions of Medical Devices Rules 2017: 60 devices

6. Classification of Medical Device pertaining to Personal Protective Equipment under the provisions of Medical Devices Rules 2017: 32 devices

7. Classification of Medical Device pertaining to General Hospital under the provisions of Medical Devices Rules 2017: 57 devices

8. Classification of Medical Device pertaining to Operation Theatre under the provisions of Medical Devices Rules 2017: 26 devices

9. Classification of Medical Device pertaining to Nephrology and Renal Care under the provisions of Medical Devices Rules 2017: 44 devices

10. Classification of Medical Device Pertaining to Dental Under the provision of Medical Devices Rules 2017: 73 devices

11. Classification of Medical Device Pertaining to Obstetrical and Gynecological Under the provision of Medical Devices Rules 2017: 107 devices

12. Classification of Medical Device Pertaining to Pediatrics and Neonatology Under the provision of Medical Devices Rules 2017: 136 devices

13. Classification of Medical Device Pertaining to Urology Under the provision of Medical Devices Rules 2017: 88 devices

14. Classification of Medical Devices Pertaining to Ophthalmology under the Provisions of Medical Devices Rules 2017: 135 devices

15. Classification of Medical Device Pertaining to Radiotherapy under the Provisions of Medical Devices Rules 2017: 101 devices

16. Classification of Medical Devices Pertaining to ENT under the Provisions of Medical Devices Rules 2017: 67 devices

17. Classification of Medical Device Pertaining to Respiratory Under the Provisions of Medical Devices Rules 2017: 51 devices

18. Classification of medical device pertaining to Cardiovascular under the provisions of Medical Devices Rules 2017: 36 devices

19. Classification of Medical Device Pertaining to Physical Support under the Provisions of Medical Devices Rules 2017: 38 devices

20. Classification of Medical Device Pertaining to Rehabilitation under the Provisions of Medical Devices Rules 2017: 48 devices

21. Classification of Medical Device Pertaining to Interventional Radiology under the Provisions of Medical Devices Rules 2017: 66 devices

22. Classification of Medical Device Pertaining to Dermatological and Plastic Surgery under the Provisions of Medical Devices Rules 2017: 55 devices

23. Classification of medical devices pertaining of Anaesthesiology under the provision of Medical Devices Rules 2017: 112 devices

24. Rheumatology: the classification of medical devices pertaining rheumatology was foreseen in 2020 but the final list was not yet published in the gazette.[2]

3.2 REGISTRATION

The registration of the non-notified products is a first step towards mandatory licensing of the products.

From **01/04/2020 till 30/09/2021,** there was a voluntary registration scheme for the non-notified products.

From **1/10/2021** all medical devices of the 24 categories have to be registered online with the Drugs Controller General of India (DCGI) by the respective importers or manufacturers.[3] Until the registration is obtained, these medical devices can't be sold or marketed in India.

When the registration number is obtained, it has to be displayed on the label.
In order to obtain the registration for medical devices, the importers and manufacturers of the medical devices have to be certified as compliant with ISO-13485 (Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes).[4]

The registration obligation comes to an end when the license regulation comes in place.

3.3 LICENSE

After the period of mandatory registration, the licensing regulation comes in place. The deadlines depend on the risk category of the products.[5]

- From **1/10/2022** importers, manufacturers, distributors, whole sellers and retailers of presently unregulated Class A (low-risk) and Class B (low-medium risk) medical devices sold in India will have to compulsorily obtain a license. The stipulated timeline for processing the license by DCGI is up to 9 months.
- From **1/10/2023** , importers and manufacturers, distributors, whole sellers and retailers of presently unregulated Class C (medium-high risk) and Class D (high risk) medical devices sold in India will have

[2] Draft list of 2020
[3] CDSCO notification
[4] Arogyalegal_all-medical-devices-in-india-to-be-regulated-as-drugs-medical-devices-amendment-rules-2020/
[5] CDSCO notification

to compulsorily obtain a license. The stipulated timeline for processing the license by DCGI is up to 9 months.

After obtaining the license, it won't expire, but a license retention fee will be due every 5 years.
For devices not produced in India, the licensing has to be initiated by an Indian company and the license will be on that company's name.

- *Importer*: The license will be on the importer's name and he will be the person importing and selling the product.
- *Consultant*: Some companies opt to have the licensing initiated by a consultant. In that way the product can be sold by several distributors and the exporter is not bound to one importer only.
- *Own branch*: opening an Indian company who will take the license.

4. PRICE MONITORING

In 2013 the Drugs Price Control Order was published, to monitor not only the quality but also the price of drugs.
This order lists numerous obligations for manufacturers and importers like Maximum Retail Price, pricing ceilings, providing data,....
In order to ensure that medical device manufacturers and importers are complying with those requirements, since February 2021 for 24 categories of products every importer/manufacturer shall submit price related information.

5. CONCLUSION

In case a product is already present on the Indian market and the product is a non-notified product, one needs to check if the importer did the necessary registration and if he has taken steps for the licensing.
For products entering the Indian market, the exporter has to decide on who's name the registration/licensing will be done.
This decision is very important because when the registration/licensing is on the importer's name, Flemish companies have to be doubly sure that the importer will expand their business actively.
In case of routing the registration process through a consultant, it gives more flexibility towards choosing distributors and if not convinced it is relatively easier to change the distributor.
Another possibility is to open a branch and register the product under the name of the branch.
As this legislation is subject to changes, you can always reach out to us at newdelhi@fitagency.com. In case you need more information, don't hesitate to a Book a Virtual Appointment with Mrs. Babette Desfossez, Trade & Investment Commissioner, Flanders Investment & Trade, New Delhi.