Dragon Sourcing

Your Tailored Approach to Emerging Markets

Newsletter VI

Syringe

July 2020

Covid-19 pandemic has spread with over 9.4 Mn cases worldwide as of 24th June 2020.

Although there is still a lot of research going on globally both, a vaccine and medication, there is still a huge demand of syringes stemming from the fact that other supplements and medication are given to

Major Suppliers of Global Syringe market include:

- B. Braun Melsungen AG (Germany)
- Becton Dickinson and Co. (USA)
- CODAN Medizinische Gerate GmbH & Co. KG (Germany)
- Gerresheimer AG (Germany)
- Henke-Sass Wolf GmbH (Germany)
- Medtronic Plc (USA, Ireland)
- NIPRO CORPORATION (Japan)
- Novo Nordisk A/S (Denmark)
- Retractable Technologies Inc. (USA)
- Terumo Corp. (Japan)
- Thermo Fisher Scientific Inc. (USA)
- Smiths Medical, Inc. (USA)
- Star Syringe Ltd (UK)
- Unilife Corporation (USA)

USA, China, France, Germany, Switzerland, Netherlands, Belgium, Italy, Singapore, and UK were among the top 10 exporting countries in 2019.

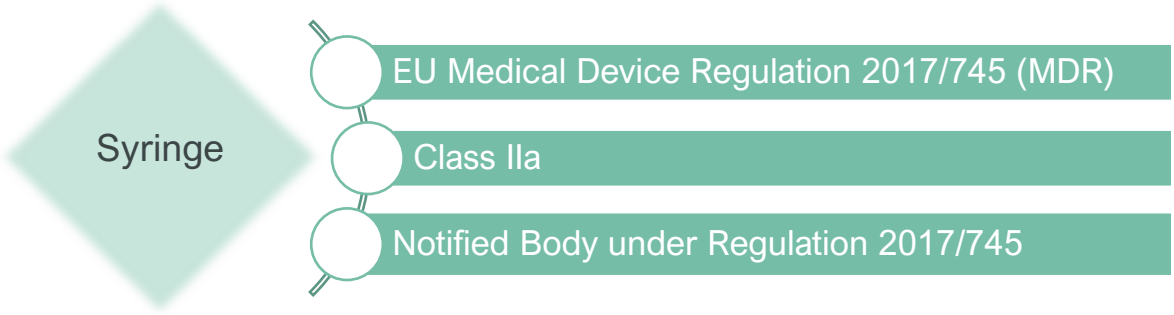
Because of Covid-19 spread, there are many production and transportation restrictions across the globe.

To combat this public health emergency, many local companies are helping with increased syringe production.

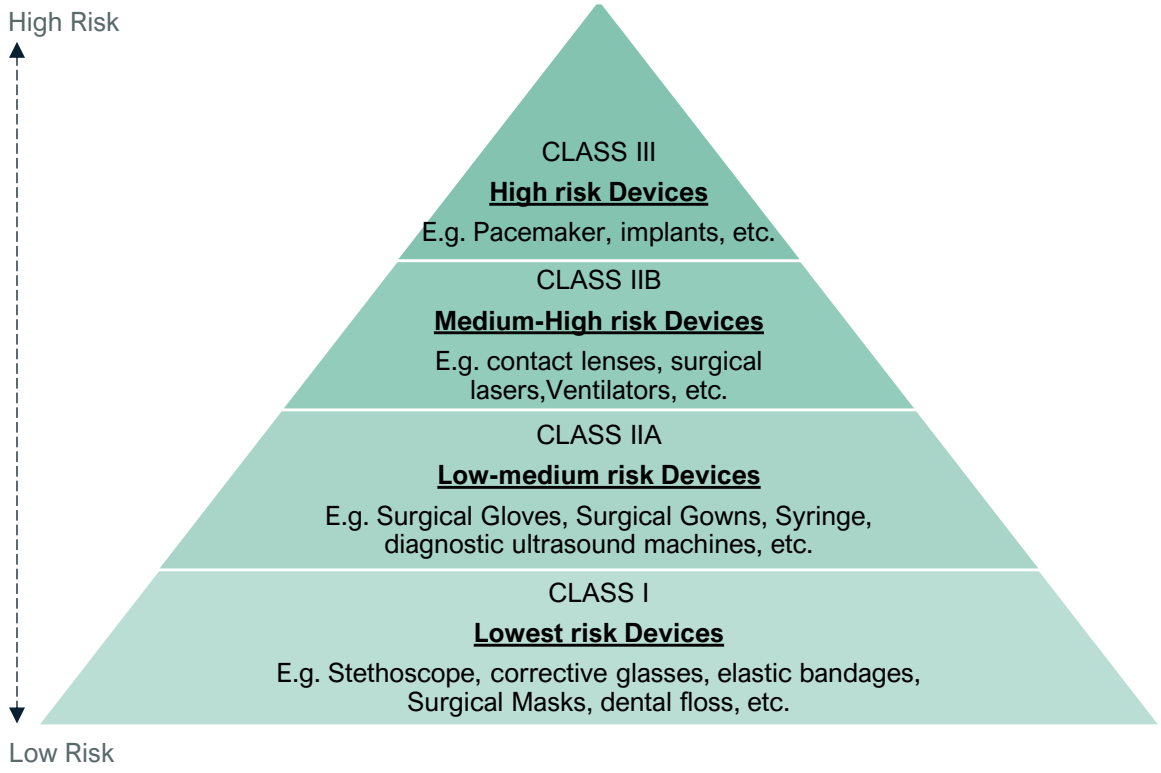
In this critical time, many fraudulent and criminal activities are detected and reported in various countries. Maximum proportion of which is cyber scams claiming to have standard medical devices and PPE, and sub-standard product sold with false certification of standards.

In both the cases, buyer can be protected with knowledge of proper standards required for that product, its procedure, and authorised entities to verify and approve that standard of that product.

EU Regulation



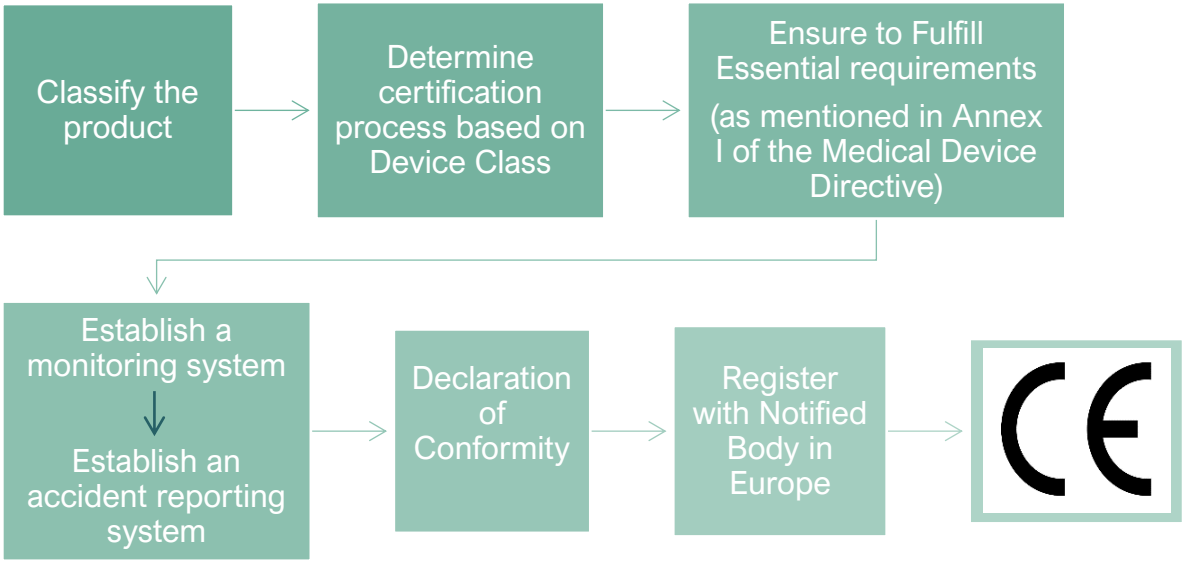
According to European Commission medical device classification, Syringe are classified as Class IIa medical device under Medical Device Directive (MDD) 93/42/EEC which is replaced by Medical Device Regulation (EU) 2017/745 (MDR).



Regulation (EU) 2017/745 of 5 May 2017 on Medical Devices and Accessories, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and replacing Council Directives 90/385/EEC and 93/42/EEC includes 3 years transitional period, which was due to be fully applicable in EU Member States from 26 May 2020. But due to Covid-19 outbreak, the European Commission has extended the transition period by one year, till 26 May 2021.

Manufacturer or Supplier can opt for either MDD 93/42/EEC or Regulation (EU) 2017/425 (if fully comply) to place medical device on the market during this transition period.

Routes for CE Mark:



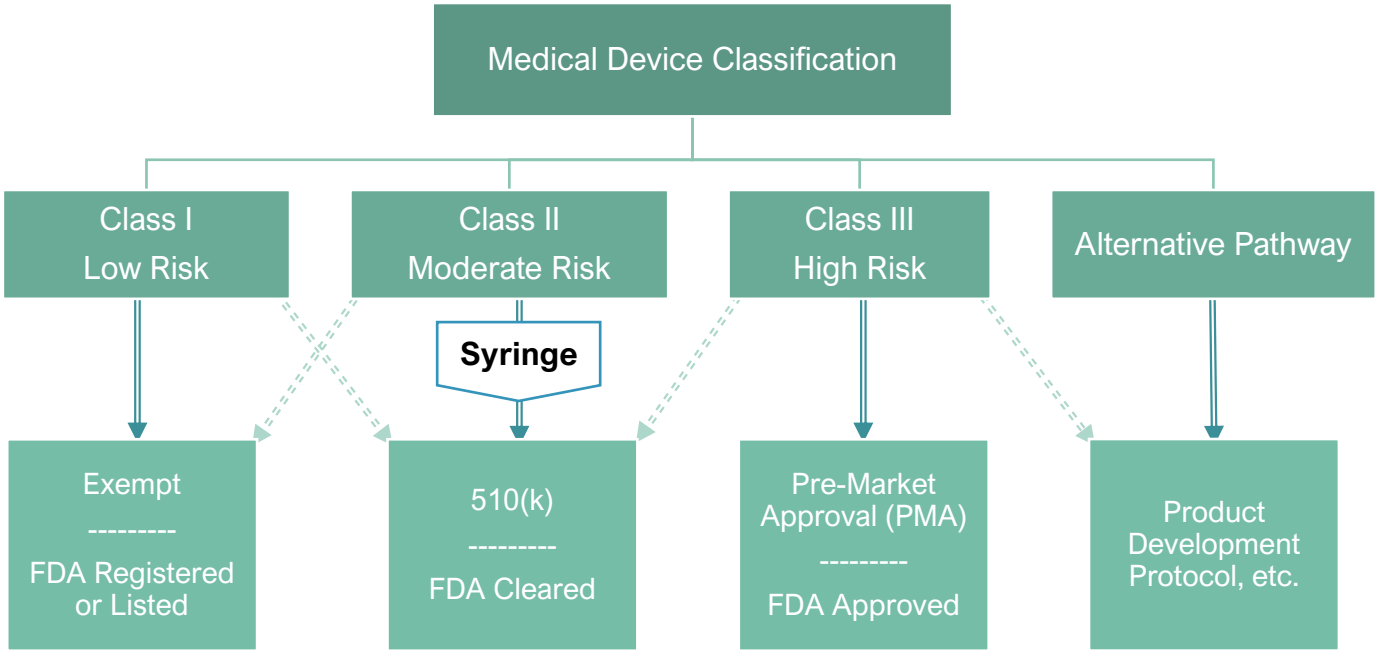
Manufacturer or supplier needs to route through complete process (as explained above) for certified CE Mark with Authorized Notified Body.

Notified Bodies for Regulation (EU) 2017/745:

Body type	Name	Country
NB 0086	BSI Assurance UK Ltd	UK
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.	Hungary
NB 1912	DARE!! Services B.V.	Netherlands
NB 0344	DEKRA Certification B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany
NB 2460	DNV GL Presafe AS	Norway
NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy
NB 2862	Intertek Medical Notified Body AB	Sweden
NB 0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	Germany
NB 0482	MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH	Germany
NB 0050	National Standards Authority of Ireland (NSAI)	Ireland
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany

Notified Bodies for MDD 93/42/EEC are listed on official European Commission website.

FDA Standards



List of different types of Syringes with Regulation Number, classified by FDA:

Product Code	Device	Device Class	Regulation Number
DQF	Actuator, Syringe, Injector Type	2	870.1670
DXT	Injector And Syringe, Angiographic	2	870.1650
ECB	Unit, Syringe, Air And/Or Water	1	872.4565
EIB	Syringe, Irrigating (Dental)	1	872.4565
EIC	Syringe, Periodontic, Endodontic, Irrigating	1	872.4565
EID	Syringe, Restorative And Impression Material	1	872.4565
EJI	Syringe, Cartridge	2	872.6770
FIH	Pump, Infusion Or Syringe, Extra-Luminal	2	876.5820
FMF	Syringe, Piston	2	880.5860
IQG	Adaptor, Holder, Syringe	1	890.5050
IWR	Holder, Syringe, Lead	1	892.6500
KCP	Syringe, Ent	1	874.5220
KYZ	Syringe, Irrigating (Non Dental)	1	880.6960
KZH	Introducer, Syringe Needle	2	880.6920
MAV	Syringe, Balloon Inflation	2	870.1650
MEG	Syringe, Antistick	2	880.5860
NKN	Syringe, Piston, Reprocessed	2	880.5860
NKT	Injector And Syringe, Angiographic, Reprocessed	2	870.1650
NKU	Injector And Syringe, Angiographic, Balloon Inflation, Reprocessed	2	870.1650
NKW	Actuator, Syringe, For Injector, Reprocessed	2	870.1670
PBU	Bone Void Filler, Syringe	Not Classified	
PGO	Anti-Stick Glass Syringe	Not Classified	
PNR	Enteral Syringes With Enteral Specific Connectors	2	876.5980
PQX	Epinephrine Syringe	2	880.5860
PTM	Syringe, Balloon Inflation, Exempt	2	870.1650
PUR	Vacuum Syringe	2	880.5860

QBL	Piston Syringe Lever	2	880.5860
QDM	Midazolam Syringe	2	880.5860
QEH	Piston Syringe With Neuraxial Connector - Epidural And Peripheral Delivery	2	880.5860

Manufacturer/Supplier must meet the requirement of 510(k) submission. Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be Substantially Equivalent (SE) and states that the device can be marketed in the US. This order "clears" the device from commercial distribution.

The 510(k) Submission Process

A 510(k) submission must be submitted in an electronic format (eCopy), should be sent to CDRH's or CBER's Document Control Center (DCC), which is available on eCopy Program for Medical Device Submissions

When the DCC receives the 510(k) submission, it assigns the submission a unique control number "510(k) number," or "K number", begins with K followed by 6 digits

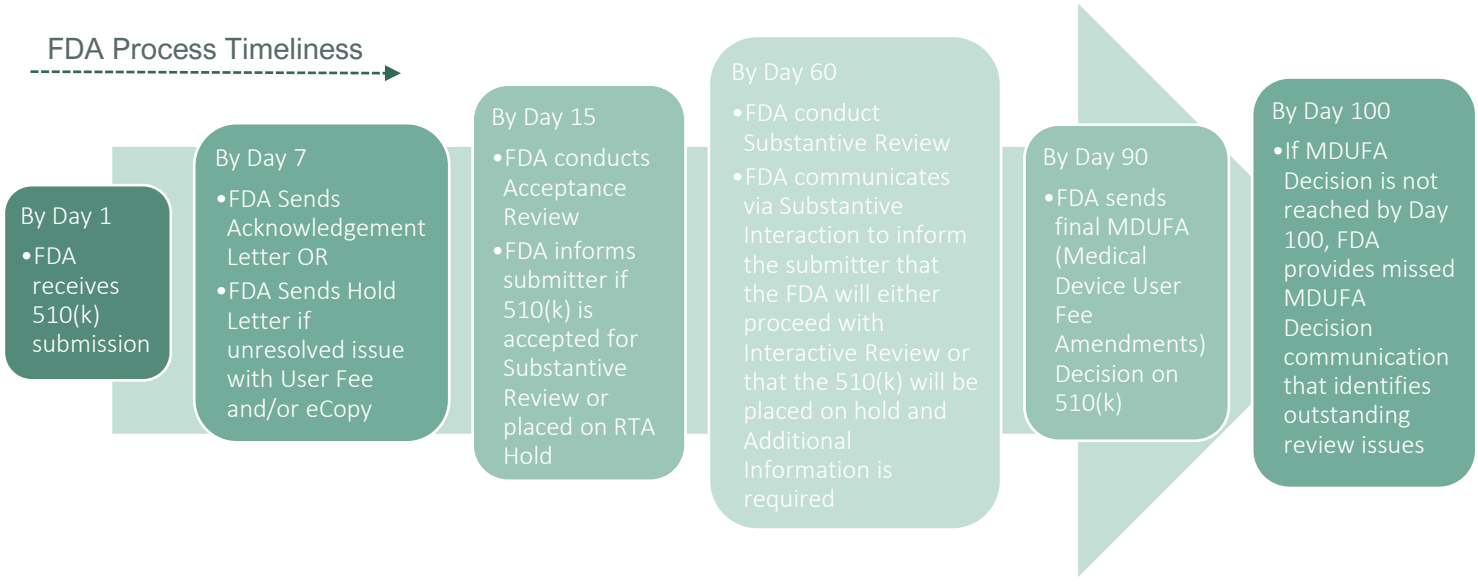
If the proper user fee has not been paid and/or a valid eCopy has not been provided, then the DCC will email a Hold Letter to the 510(k) submitter, usually within 7 days of receipt of the 510(k). Submitter needs to resolve it within 180 days. If not resolved, it will be considered as withdrawn and has to submit new 510(k) FDA marketing clearance

After the Acknowledgement Letter is sent, the DCC routes the 510(k) to the appropriate ODE or OIR Division

Within 15 days of the receipt of the submission, the submitter will receive an electronic notification of the Acceptance Review result, which will: Identify name & contact information of FDA Lead Reviewer and Indicate the status

If the Lead Reviewer sends an AI (Additional Information) Request, the submission is placed on hold. The submitter must submit the response, with a valid eCopy, to the DCC within 180 calendar days of the date of the AI Request; including the submitter's name; 510(k) number; identify the submission as Additional Information (AI) to the 510(k); date of FDA's request for AI and provide the requested information in an organized manner

When a decision is made, FDA will issue the decision letter to the submitter by email to the email address provided in the 510(k) cover letter. A 510(k) that receives an SE decision is considered "cleared." And submitter will be added in the 510(k) database, which is updated weekly.



Compliance Check

FDA Compliance:

- FDA approved or cleared suppliers are listed on official FDA website under Establishment Registration & Device Listing section and are weekly updated.
- Suppliers authorized under EUA are listed and updated on EUA page for particular product category on FDA website.
- Third Party Reviewers are mentioned and updated on FDA website along with the product category they are permitted to review by FDA.

CE mark Compliance:

- There is no central database for CE marks and Notified bodies certificate. Only Notified body who issued the certificate can validate it.
- Notified Bodies are listed under each legislation on official European Commission website.
- Not each Notified Bodies can certify any product. Notified Bodies listed under particular legislation are authorized to certify the range of products lying under that legislation only.

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