醫療用品及個人防護裝備- 品質系統、測試及驗證

- Medical Devices and Personal Protective Equipment – Quality Management

SGS Hong Kong Limited | 陳冠宇 Birkoff CHEN | 29th October 2020

In partnership with

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Content

- Anti-pandemic Products
- PPE Products
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- Standards and Testing
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Anti-pandemic Products

Medical Devices

- Surgical face masks
- Surgical gowns
- Thermometers

…etc.

COVID-19 protection products are commonly falls under the supervision of the Medical Devices or Personal Protective Equipment Regulations or Directives

Personal Protective Equipment (PPE)

- Respirators
- Face shields
- Goggles

…etc.

What is PPE? (Article 1)

> *Any device or appliance designed to be worn or held by an individual for protection against one or more safety hazards*
>
> *Regulation (EU) 2016/425*

What is not PPE?

- For head, face or eye protection of users covered by Regulation No. 22 of the United Nations Economic Commission for Europe on uniform provisions concerning the approval of protective helmets and their visors for drivers and passengers of motor cycles and mopeds

What is not PPE?

- Specifically designed for use by the armed forces or for the maintenance of law and order
- Designed to be used for self-defence, with the exception of PPE intended for sporting activities
- Intended for private use to protect against
  - Atmospheric conditions that are not of an extreme nature
  - Dam and water during dishwashing
- For exclusive use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable in member states

PPE Regulation (EU) 2016/425

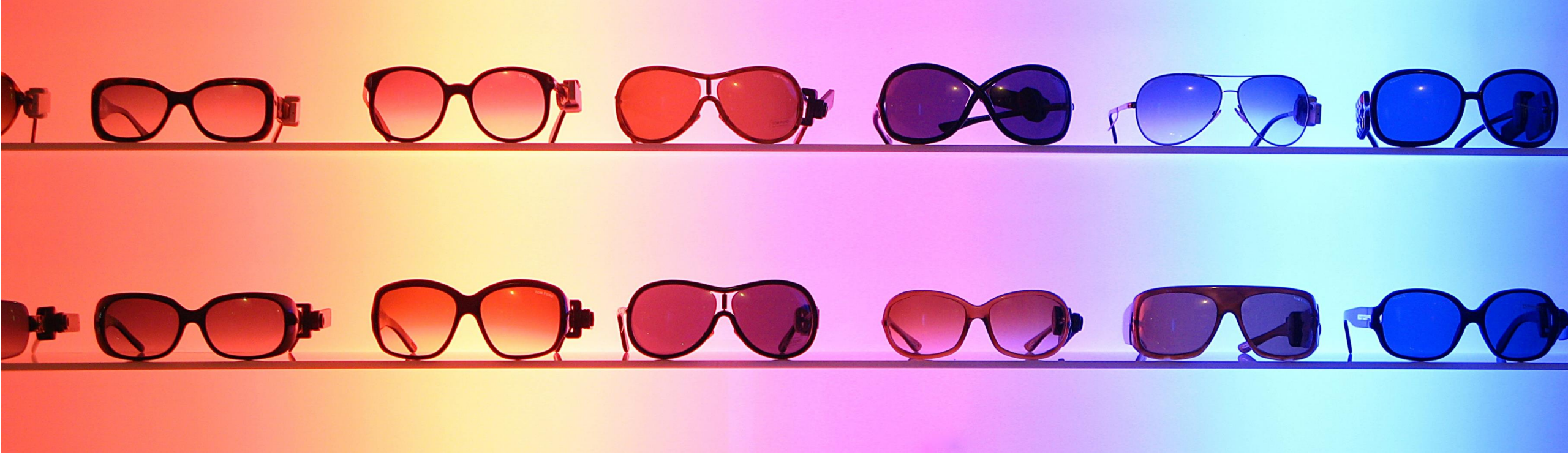
- March 31, 2016, Personal Protective Equipment Regulation (EU) 2016/425 published
- April 21, 2018, previous Directive 89/686/EEC withdrawn
- April 21, 2019, all newly launched PPE products must meet the requirements of (EU) 2016/425
- April 21, 2023, the EC Type Examination Certificate (Article 10) under Directive 89/686/EEC is still valid if it has not expired before that date

This regulation applies to, for example,

- Disposable and reusable respirators/face masks against solid particles
- Disposable and reusable protective clothing
- Gloves and goggles for the prevention and protection of harmful biological agents such as viruses, etc.

PPE Categories I, II or III

- The Regulation (EU) 2016/425 is split into three categories which are based on the risk involved to the user
  - Category I – Simple PPE
  - Category II – Intermediate PPE
  - Category III – Complex PPE



Category I

- Minimal Risk
  - Examples –
    - Superficial mechanical injury
    - Contact with hot surfaces not exceeding 50 degrees Celsius
    - Natural UV Light

Category III

- Risks that may cause very serious consequences such as death or irreversible damage to health
  - Examples –
    - Substances and mixtures which are hazardous to health
    - Atmospheres with oxygen deficiency
    - harmful biological agents
    - Ionising radiation
    - Falling from a height
    - Electric shock and live working
    - Cuts by hand-held chainsaws
    - Drowning
    - High-pressure jets
    - Harmful noise

Category II

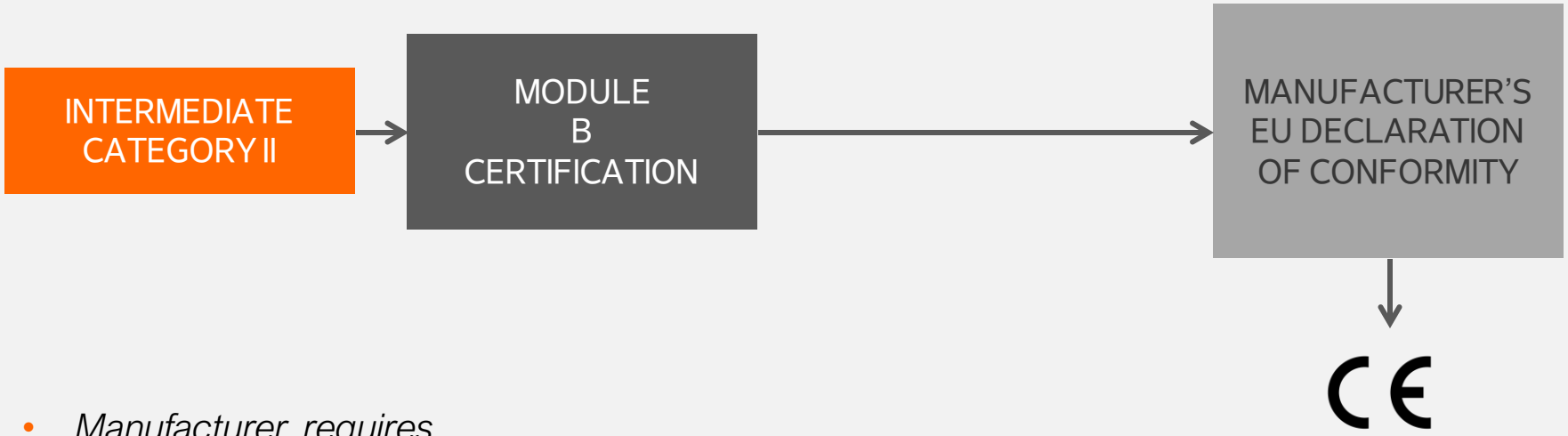
- Neither Category I nor III
  - Examples –
    - Safety and sports helmets
    - High visibility clothing
    - Protection against serious mechanical injury, e.g. metal working gloves, safety footwear
    - Buoyancy aids
    - Immersion suits/wet suits
    - Motorcycle clothing & high risk sports protective equipment

FLOW CHART – CATEGORY I

SIMPLE CATEGORY I → MANUFACTURER'S EU DECLARATION OF CONFORMITY → CE

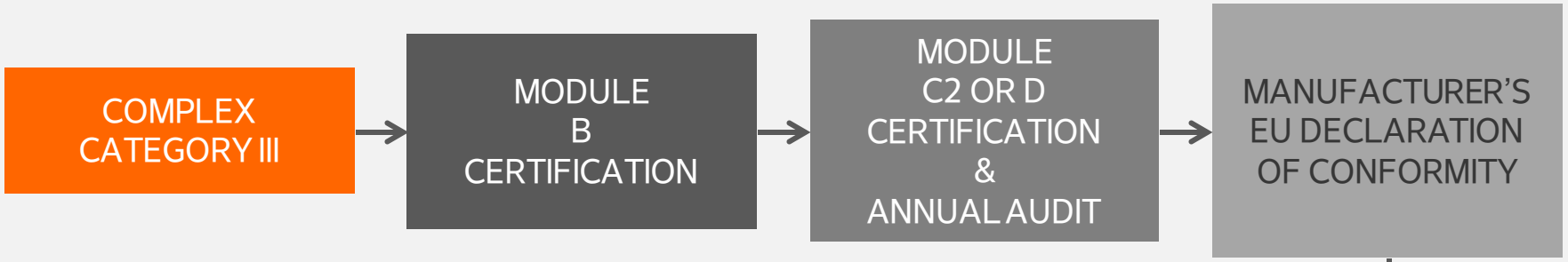
- *No requirement for Notified Body involvement*
- *Manufacturer requires*
  - *Testing to the required standard by an accredited lab*
  - *Technical file*
- *Self declaration by means of an EU Declaration of Conformity*

FLOW CHART – CATEGORY II



- *Manufacturer requires*
  - *Testing to the required standard by an accredited lab*
  - *Technical file*
- *Module B certification from Notified Body*

FLOW CHART – CATEGORY III



CE 0598

- *Manufacturer requires*
  - *Testing to the required standard by an accredited lab*
  - *Technical file*
- *Module B certification from Notified Body for Cat II & Cat III*
  - *Module C2 or D certification from Notified Body for Cat III*

What is Medical Devices?

“…any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more defined specific medical purposes.”

Regulation (EU) 2017/745

Medical Devices Regulations in the EU

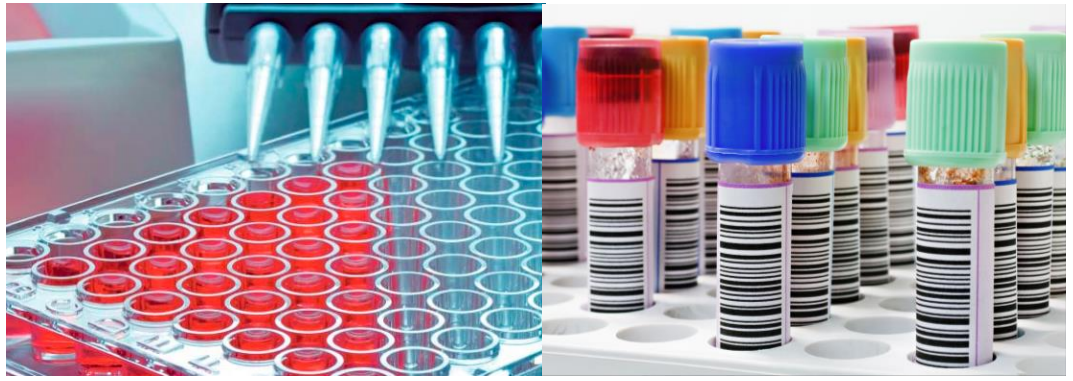
Medical Devices Regulation (EU) 2017/745

Published on May 5, 2017

Transition period until May 26, 2021

Current: Medical Device Directive 93/42/EEC

Examples: surgical face masks, surgical gown, clinical thermometer, etc.



In Vitro Diagnostic Devices Regulation (EU) 2017/746

Published on May 5, 2017

Transition period until May 26, 2022

Current: In Vitro Diagnostic Medical Devices Directive 98/79/EC

Examples: reagents, reagent products, test kits, sample containers, etc.

Transition Timeline

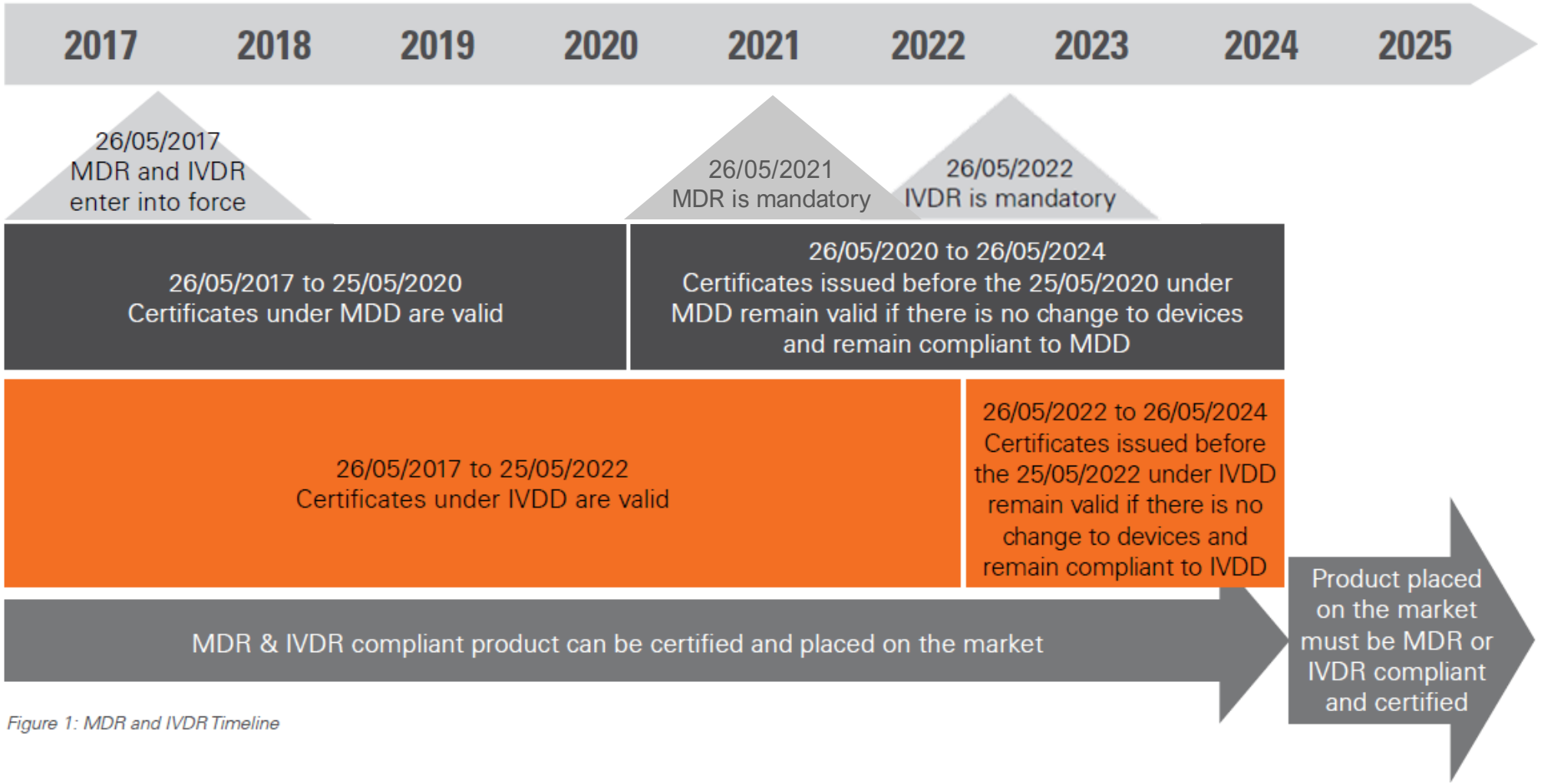
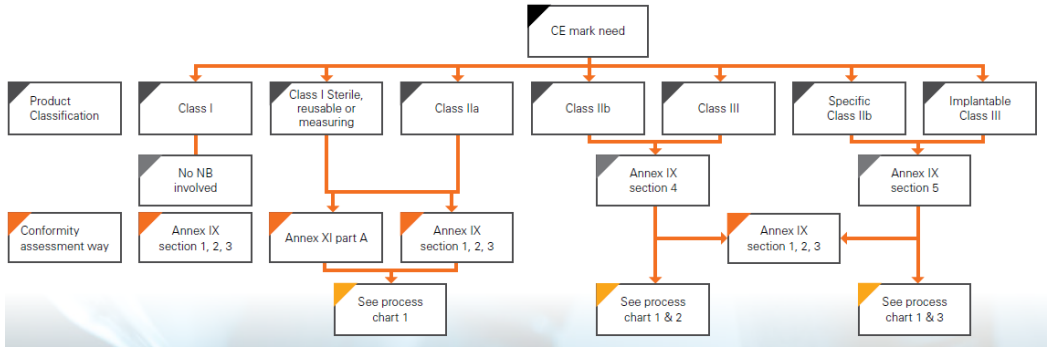


Figure 1: MDR and IVDR Timeline

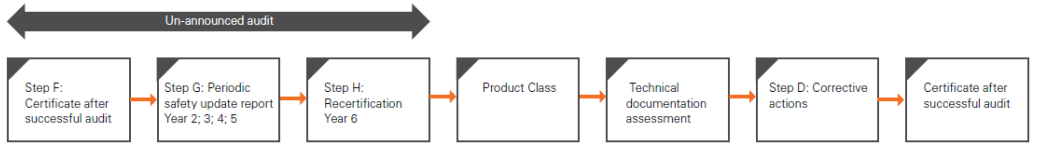
CE Process - MDR (EU) 2017/745



PROCESS CHART 1

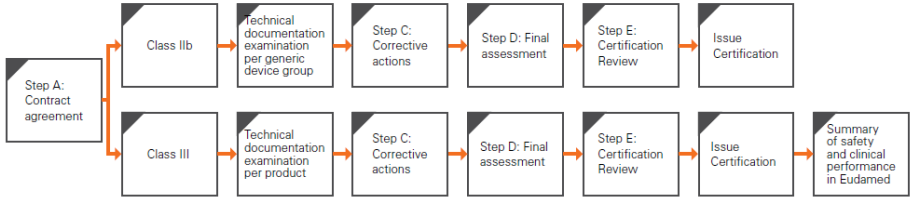
INITIAL ASSESSMENT

CERTIFICATION CYCLE



PROCESS CHART 2

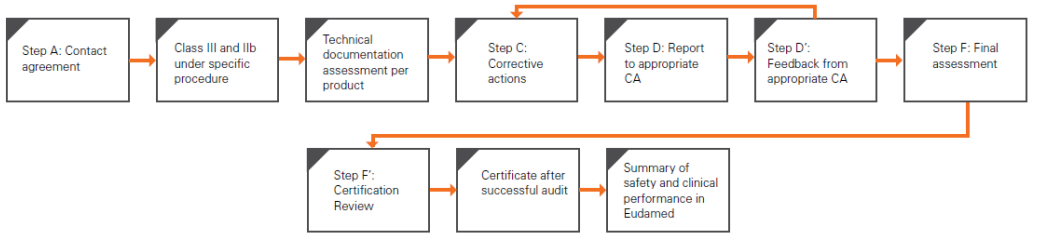
INITIAL ASSESSMENT



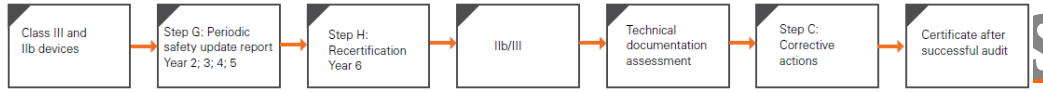
CERTIFICATION CYCLE

PROCESS CHART 3

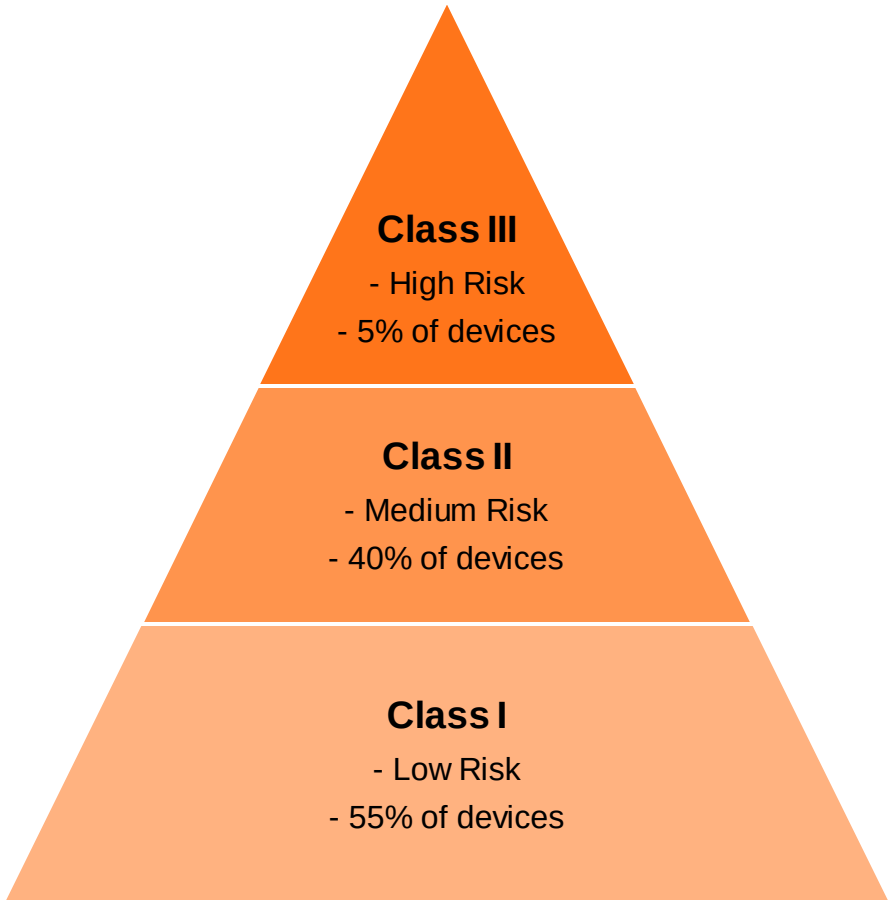
INITIAL ASSESSMENT



CERTIFICATION CYCLE



FDA Process - 510(k) Premarket Notification

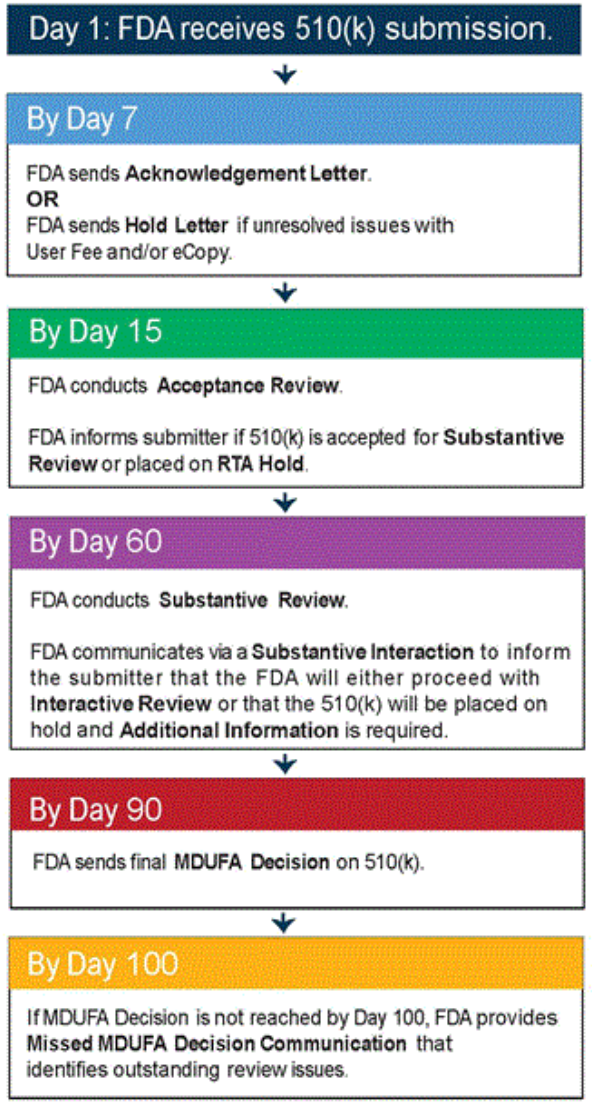


Class II Medical Devices

- Contact FDA
- A premarket 510(k) premarket notification must be submitted to FDA to review and provide clearance to the medical device.
  - 510(k) → Critical
- Some medical devices based on their FDA Product code are exempt from 510(k).

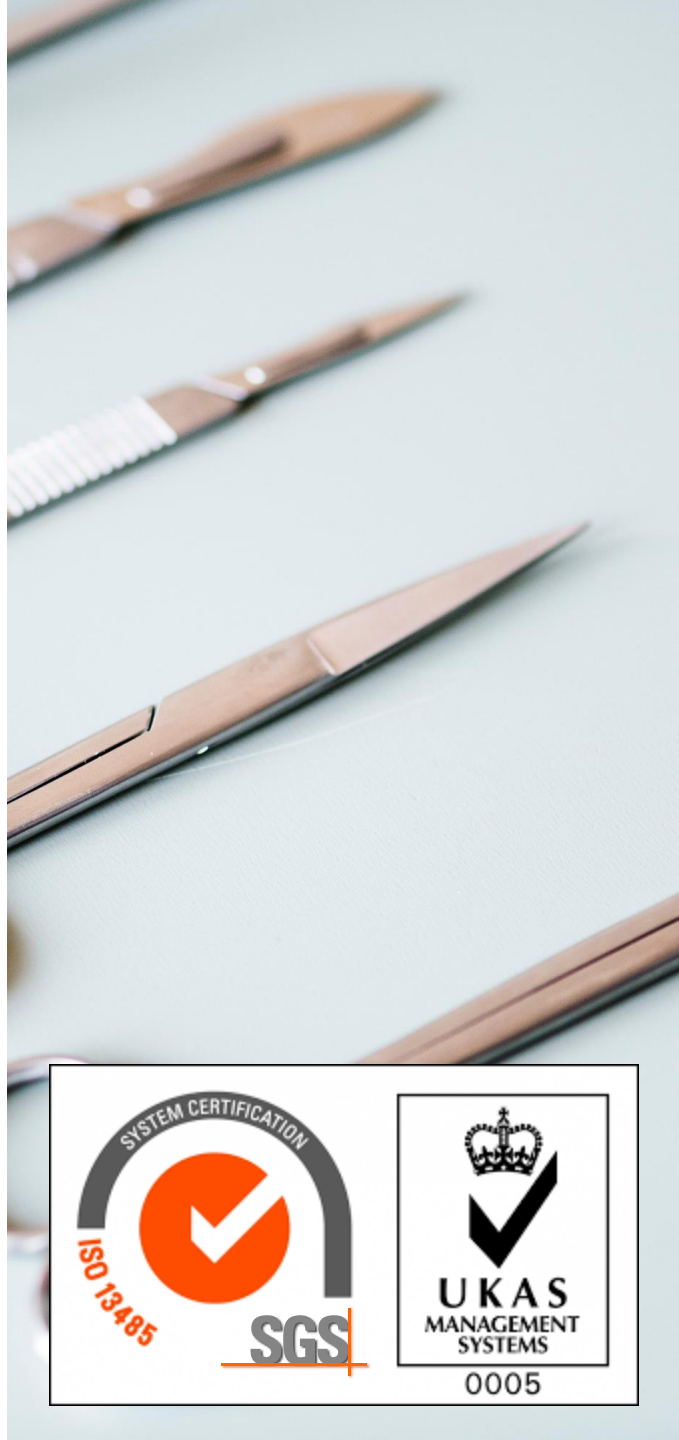
FDA Process - 510(k) Premarket Notification

- FDA assigns product codes (e.g. FXX) to a product type, these codes will determine
  - Applicable requirements
  - Device Class (e.g. Class ll),
  - Submission Type (e.g. 510(k)),
  - Recognized Consensus Standards (e.g. ASTM F2100).
- 21 CFR Part 807
  - FDA Registration
  - Medical Device Listing - 21 CFR Part 807



ISO 13485:2016

- *Medical devices – Quality management systems – Requirements for regulatory purposes*, is an internationally agreed standard that sets out the requirements for a quality management system (QMS) specific to the medical devices industry including
  - Manufacturers
  - Service Providers (outsourced processes)
- Ensures that key stakeholders in medical device industry demonstrate their compliance to regulatory requirements
- Similar in scope and intent to ISO 9001 but have additional requirements specific to organizations involved in the life cycle of medical devices and remove irrelevant elements



Standards and Testing

- The EU Regulations establish
  - General safety and performance requirements but are technically neutral
  - Do not lay down specific mandatory solutions for product design

Therefore, manufacturers can use various technical solution if deem acceptable to meet these essential requirements

Standards and Testing

- Both PPE and MDD provide specific technical solution through
  - EU Official Journal, and
  - Harmonized standards

If the manufacturer chooses to adopt these technical solutions, the product is presumed to meet the applicable basic hygiene, safety and performance requirements set in the relevant Regulations.

Standards and Testing

Harmonized standards for masks, for example

- FFP respirator, EN 149:2001+A1:2009
- Surgical face mask, EN 14683:2019+AC:2019

Manufacturers are suggested following the harmonized standards to demonstrate compliance to the Regulations for achieving faster marketability

Example 1

Disposable Surgical Face Masks

Medical Devices Directive 93/42/EEC and Medical Devices Regulation (EU) 2017/745

FDA 21 CFR 878.4040

Disposable Surgical Face Masks

- EU Member States
  - Class 1 Medical Device
  - MDD 93/42/EEC and MDR (EU) 2017/745
  - Requires CE marking (Self declaration)
  - EN 14683:2019+AC:2019
    - Type I, II & IIR
    - Bacterial Filtration Efficiency (BFE)
    - Breathability
    - Fluid Resistance
    - Microbial Cleanliness
    - Biocompatibility

Example 1

Disposable Surgical Face Masks

- United States
  - Class II Medical Devices
  - FDA 21 CFR 878.4040
  - Requires 510(k) pre-market notification and FDA product code FXX
  - ASTM F2100:2019
    - Level 1, 2 & 3
    - Bacterial Filtration Efficiency (BFE)
    - Particle Filtration Efficiency (PFE)
    - Differential Pressure
    - Synthetic Blood Penetration
    - Flame Spread

Example 1

Example 2

Disposable Respirators

Personal Protective Equipment Regulation (EU) 2016/425

NIOSH Subpart K of 42 CFR Part 84

Disposable Respirators

- EU Member States
  - Category III PPE
  - PPER (EU) 2016/425
  - Requires CE marking (Notified Body, e.g. Module B Audit)
  - EN 149
    - FFP 1, 2 & 3
    - Particle Filtration
    - Airflow Resistance
    - Exhalation Valve Leakage

    …etc.

Disposable Respirators

- United States
  - CDC's NIOSH and OSHA regulate N95's
  - Subpart K of 42 CFR Part 84
  - Required NIOSH Certified Equipment
  - Manufacturers must apply for NIOSH approval by submitting
    - performance tests in Subpart K of 42 CFR Part 84
    - drawings, packaging and label copy, detailed user instructions
    - a product quality plan, and
    - a quality assurance manual for its manufacturing facility

Example 2

Example 3

Sunglasses

Personal Protective Equipment Regulation (EU) 2016/425

FDA 21 CFR 801.410

Sunglasses

- EU Member States
  - Category I PPE
  - PPER (EU) 2016/425
  - Requires CE marking (Self declaration)
  - EN ISO 12312-1: 2013+ A1: 2015
    - Transmittance and Filter Category
    - Traffic Signal
    - Refractive Power
    - Minimum Robustness
    - Impact Resistance

    …etc.

Sunglasses

- United States
  - FDA Class I Medical Device
  - 21 CFR 801.410 Impact Resistance
  - ANSI Z80.3: 2018
    - UV Transmittance
    - Refractive/Astigmatic/Prismatic Power
    - Luminous Transmittance
    - Traffic Signal
    - Impact Resistance
    - Flammability

    …etc.

Example 3

Thank you!

Do you have any questions?

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