Dipartimento di Ingegneria e Architettura

CEI CENTRAL EUROPEAN INITIATIVE

BioingTS

New European Regulations, MDR and IVDR

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MedTech Projects

UNIVERSITÀ DEGLI STUDI DI TRIESTE

comune di trieste

ORDINE DEGLI INGEGNERI PROVINCIA DI TRIESTE

IFMBE

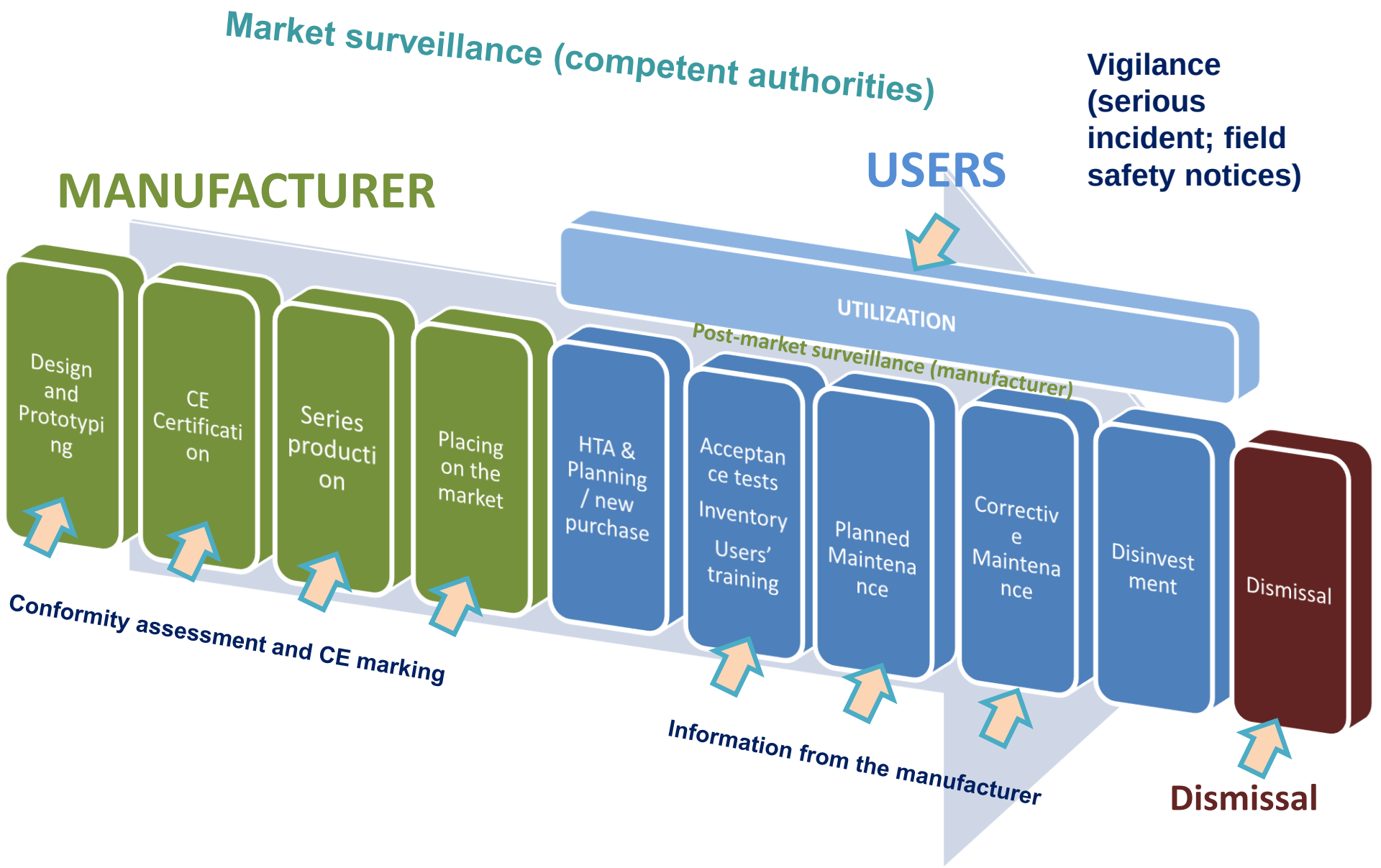
AIIC associazione italiana ingegneri clinici

FROM THE MEDICAL DEVICE DIRECTIVES TO THE NEW (EU) REGULATIONS 2017/745 AND 2017/746

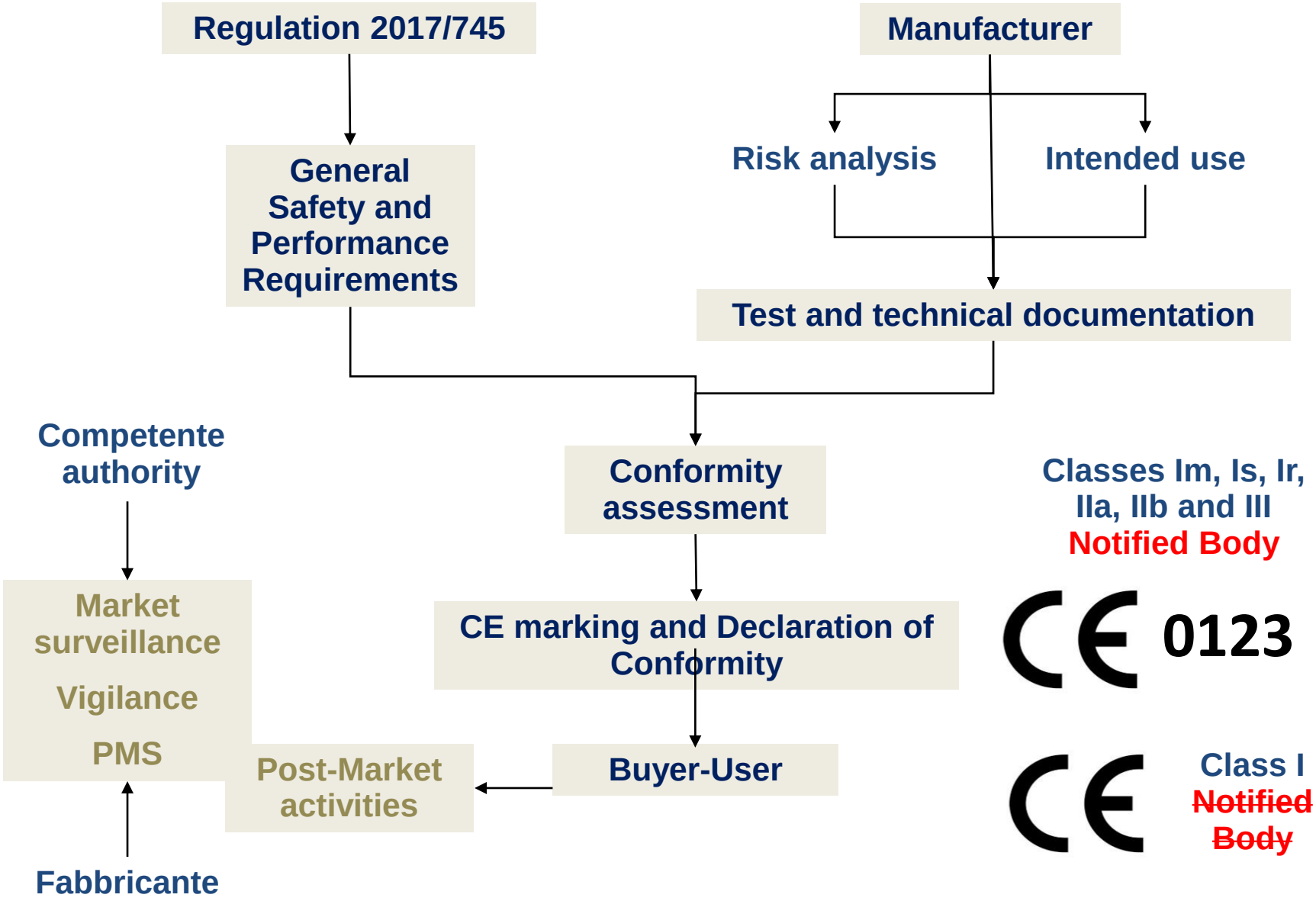
MedTech Projects

UNIVERSITÀ DEGLI STUDI DI TRIESTE

«Life cycle» of medical technologies



Certification of medical devices

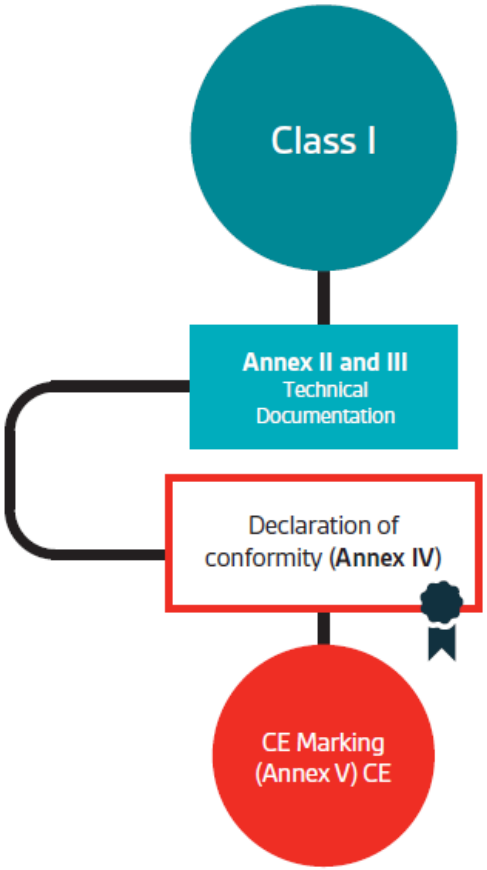


Certification of medical devices

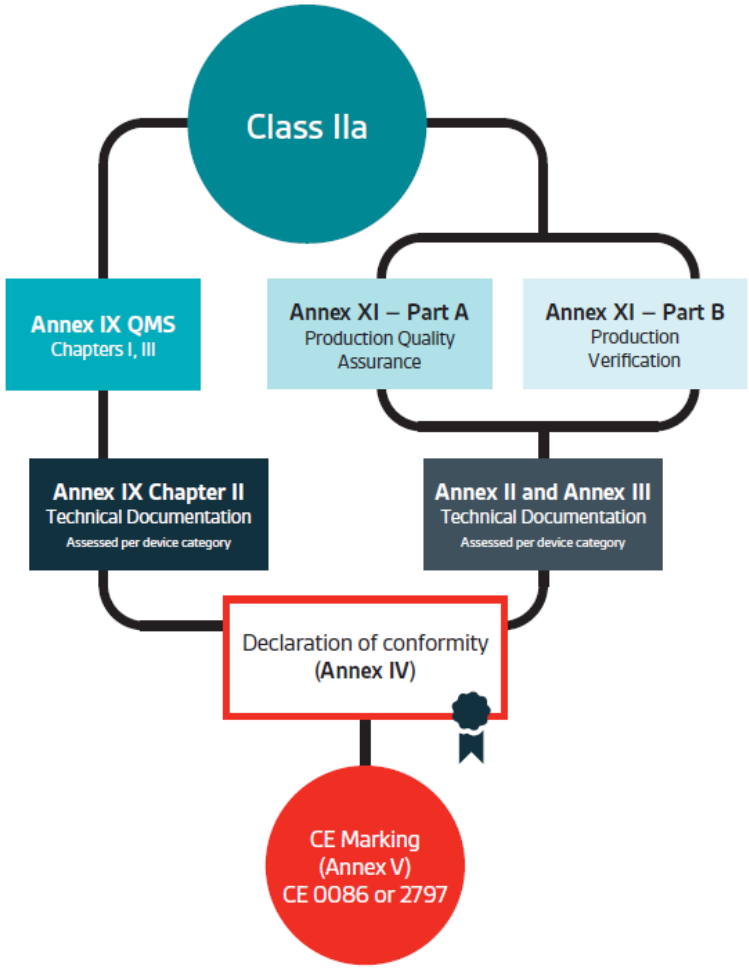
Class I devices

(excluding Class Is/Im/Ir devices)

Note: No Notified Body involvement



Class IIa devices



CE certificates vs. Declaration of Conformity

CE Certificates and Declarations of Conformity

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 102669 0006 Rev. 00

Manufacturer: **Getinge Disinfection AB**
Ljungadalsgatan 11
352 46 Växjö
SWEDEN

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 102669 0006 Rev. 00

Report No.: 713183533

Valid from: 2021-05-18
Valid until: 2026-05-17

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-05-18

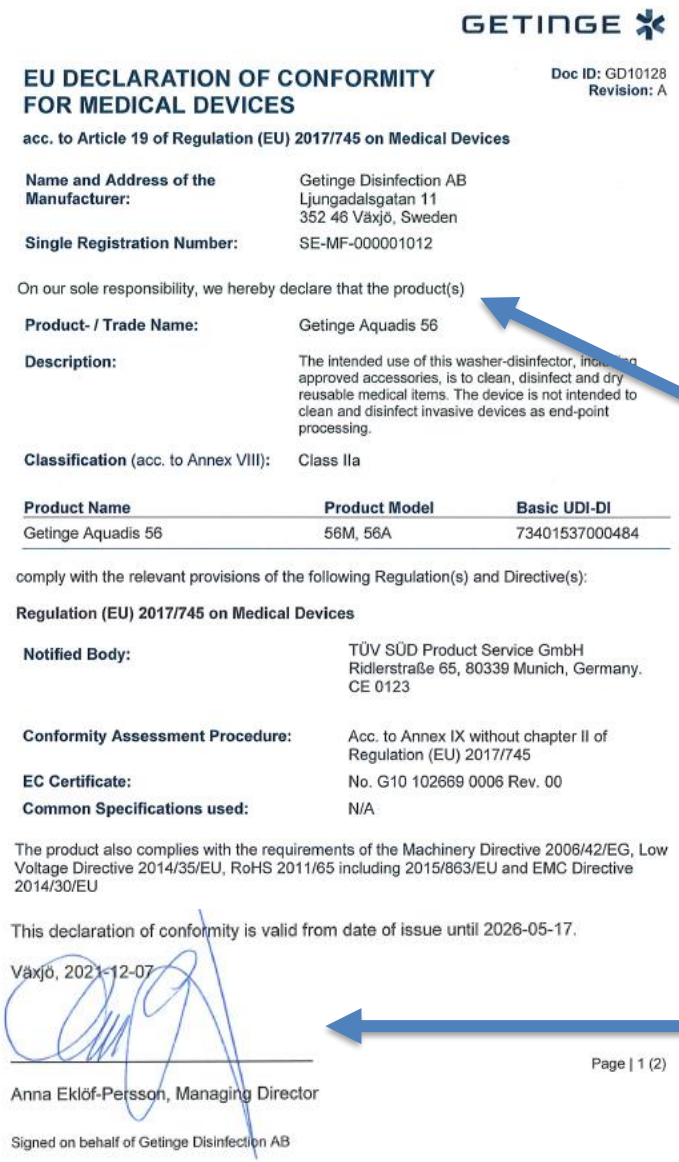
Page 1 of 2
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

CE Certificate

Released by a Notified Body!!

CE Certificates and Declarations of Conformity



GETINGE

EU DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

Doc ID: GD10128
Revision: A

acc. to Article 19 of Regulation (EU) 2017/745 on Medical Devices

Name and Address of the Manufacturer:	Getinge Disinfection AB Ljungadalsgatan 11 352 46 Växjö, Sweden
Single Registration Number:	SE-MF-000001012

On our sole responsibility, we hereby declare that the product(s)

Product- / Trade Name:	Getinge Aquadis 56
Description:	The intended use of this washer-disinfector, including approved accessories, is to clean, disinfect and dry reusable medical items. The device is not intended to clean and disinfect invasive devices as end-point processing.
Classification (acc. to Annex VIII):	Class IIa

Product Name	Product Model	Basic UDI-DI
Getinge Aquadis 56	56M, 56A	73401537000484

comply with the relevant provisions of the following Regulation(s) and Directive(s):

Regulation (EU) 2017/745 on Medical Devices

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany. CE 0123
Conformity Assessment Procedure:	Acc. to Annex IX without chapter II of Regulation (EU) 2017/745
EC Certificate:	No. G10 102669 0006 Rev. 00
Common Specifications used:	N/A

The product also complies with the requirements of the Machinery Directive 2006/42/EG, Low Voltage Directive 2014/35/EU, RoHS 2011/65 including 2015/863/EU and EMC Directive 2014/30/EU

This declaration of conformity is valid from date of issue until 2026-05-17.

Växjö, 2021-12-07

Page | 1 (2)

Anna Eklöf-Persson, Managing Director

Signed on behalf of Getinge Disinfection AB

Declaration of Conformity

Released by the Manufacturer!!

Assumption of responsibility

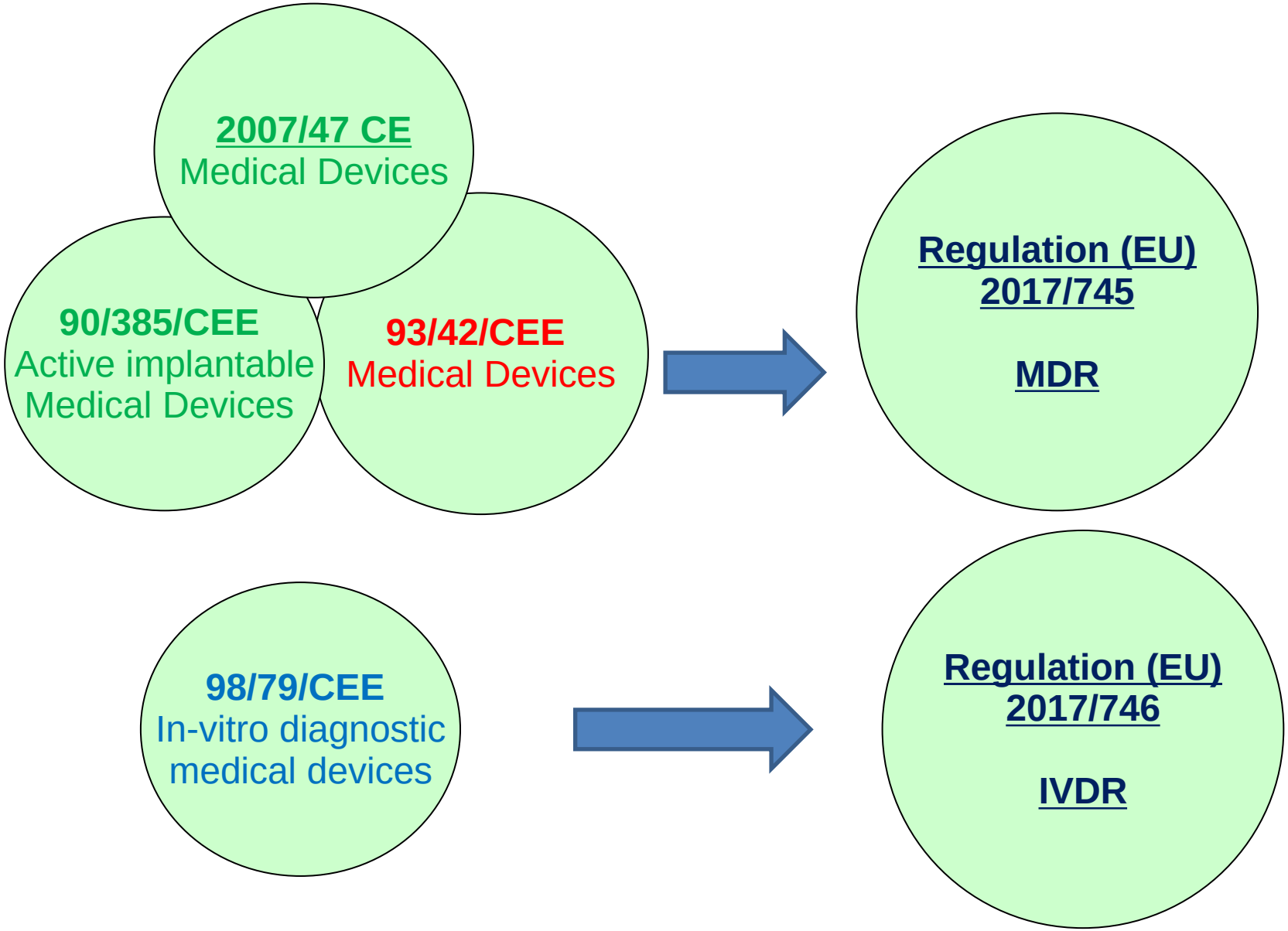
Reference to the CE Certificate

Signed by a representative of the Manufacturer

Main context

Common rules allow same certification rules and free circulation of products

Main context



Main context

1990	Dir. 90/385 – D.Lgs 507/92 (Active implantable devices)
1993	Dir. 93/42 – D.Lgs 46/97 (Medical devices)
1998	Dir. 98/79 – D.Lgs 332/2000 (In vitro diagnostic medical devices)
2007	Dir. 2007/47 – D.Lgs 37/2010 (modifications MDs)
2012	Draft proposal of new Regulations
2017	Adoption of new Regulations 2017/745 – 2017/746
2021	Application of Regulation 2017/745
…	

Regulation (EU) 2017/745 – Medical Devices

5.5.2017 EN Official Journal of the European Union L 117/1

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

(Text with EEA relevance)

We'll go in detail of the main news of this Regulation

Regulation (EU) 2017/746 – In vitro diagnostic medical devices

L 117/176 EN Official Journal of the European Union 5.5.2017

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

(Text with EEA relevance)

We'll not detail the Regulation (EU) 2017/746 on in vitro diagnostic medical devices

The structure of Regulation (EU) 2017/745

Section	Regulation (EU) 2017/745	Directive 93/42 Medical Devices	Directive 90/385 Implantable Active Medical Devices
Whereas	101	22	12
Definitions	71	13	7
Articles	123	22	17
Annexes	17	12	9

Much bigger and more detailed legislative text

The evolution of Regulation (EU) 2017/745

5.5.2017 IT Gazzetta ufficiale dell'Unione europea L 117/1

I

(Atti legislativi)

REGOLAMENTI

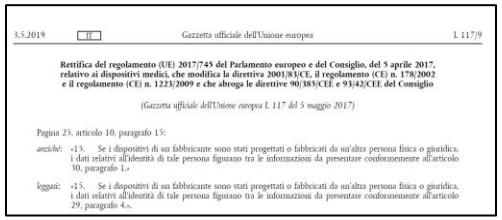
REGOLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO

del 5 aprile 2017

relativo ai dispositivi medici, che modifica la direttiva 2001/83/CE, il regolamento (CE) n. 178/2002 e il regolamento (CE) n. 1223/2009 e che abroga le direttive 90/385/CEE e 93/42/CEE del Consiglio

(Testo rilevante ai fini del SEE)

Regulation 2017/745 published in EU Official Journal 5th May 2017



3.5.2019 IT Gazzetta ufficiale dell'Unione europea L 117/9

Rettifica del regolamento (UE) 2017/745 del Parlamento europeo e del Consiglio, del 5 aprile 2017, relativo ai dispositivi medici, che modifica la direttiva 2001/83/CE, il regolamento (CE) n. 178/2002 e il regolamento (CE) n. 1223/2009 e che abroga le direttive 90/385/CEE e 93/42/CEE del Consiglio

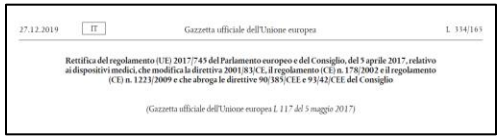
(Gazzetta ufficiale dell'Unione europea L 117 del 5 maggio 2017)

Pagina 25, articolo 10, paragrafo 15:

anziché: «15. Se i dispositivi di un fabbricante sono stati progettati o fabbricati da un'altra persona fisica o giuridica, i dati relativi all'identità di tale persona figurano tra le informazioni da presentare conformemente all'articolo 10, paragrafo 1.»

leggasi: «15. Se i dispositivi di un fabbricante sono stati progettati o fabbricati da un'altra persona fisica o giuridica, i dati relativi all'identità di tale persona figurano tra le informazioni da presentare conformemente all'articolo 29, paragrafo 4.».

Corrigendum of 3rd May 2019 (formal errors, various corrections)



27.12.2019 IT Gazzetta ufficiale dell'Unione europea L 334/163

Rettifica del regolamento (UE) 2017/745 del Parlamento europeo e del Consiglio, del 5 aprile 2017, relativo ai dispositivi medici, che modifica la direttiva 2001/83/CE, il regolamento (CE) n. 178/2002 e il regolamento (CE) n. 1223/2009 e che abroga le direttive 90/385/CEE e 93/42/CEE del Consiglio

(Gazzetta ufficiale dell'Unione europea L 117 del 5 maggio 2017)

Corrigendum of 27th December 2019 (IMPORTANT: inclusion of Class I MD in the transition rules of Art. 120)

L 130/18 IT Gazzetta ufficiale dell'Unione europea 24.4.2020

REGOLAMENTO (UE) 2020/561 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO

del 23 aprile 2020

che modifica il regolamento (UE) 2017/745 relativo ai dispositivi medici, per quanto riguarda le date di applicazione di alcune delle sue disposizioni

(Testo rilevante ai fini del SEE)

Regulation 2020/561 published in EU Official Journal 24th April 2020 (application date moved to May 2021)

The evolution of Regulation (EU) 2017/745

L 80/24 EN Official Journal of the European Union 20.3.2023

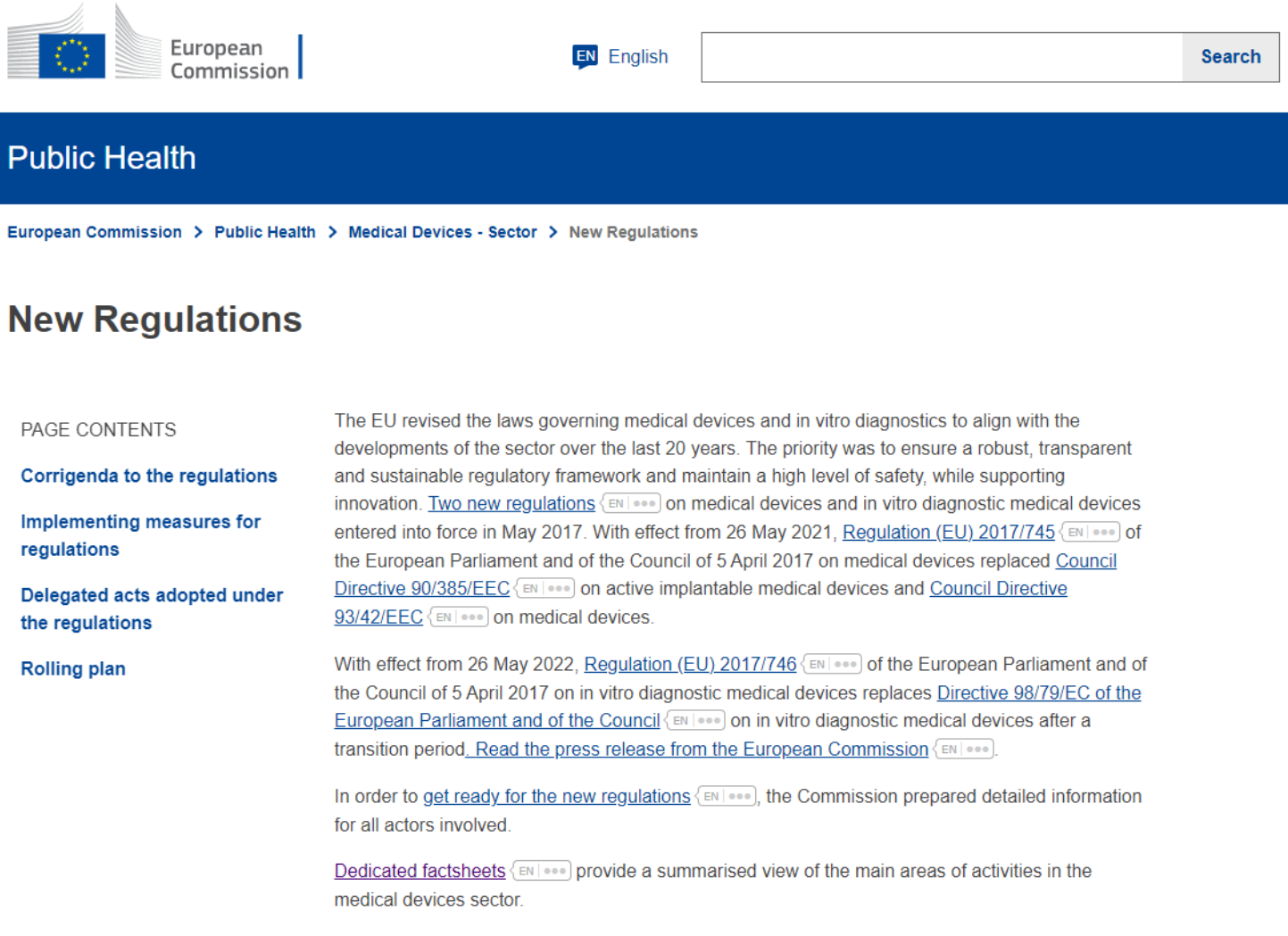
REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 March 2023

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices

(Text with EEA relevance)

WHERE YOU CAN FIND INFORMATION ADN UPDATES



https://ec.europa.eu/health/medical-devices-sector/new-regulations_en

Information, documentation, updates

Commissione europea

italiano Cerca

Public Health

Questa pagina non è disponibile in italiano. Chiudi il messaggio

Scegliere un'altra lingua | Traduci questa pagina

Commissione europea > Public Health > Dispositivi Medici - Settore > New Regulations > Guidance

Guidance - MDCG endorsed documents and other guidance

INDICE

- MDCG work in progress
- Borderline and Classification
- Class I Devices
- Clinical investigation and evaluation
- COVID-19
- Custom-Made Devices
- EUDAMED
- European Medical Device Nomenclature (EMDN)
- Implant cards
- Importers & Distributors
- In Vitro Diagnostic medical

This page provides a range of documents to assist stakeholders in applying Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 (IVDR) on in vitro diagnostic medical devices. The majority of documents on this page are endorsed by the Medical Device Coordination Group (MDCG) in accordance with Article 105 of the MDR and Article 99 of the IVDR. They are drafted in collaboration with interested parties represented in the various groups and denominated by the following format: "MDCG Year-Number-revision".

The documents on this page are not legally binding. They present a common understanding of how the MDR and IVDR should be applied in practice aiming at an effective and harmonised implementation of the legislation.

MDCG work in progress

Ongoing guidance documents

Borderline and Classification

Reference	Title	Publication
MDCG 2022-5		

Article 103

Medical Device Coordination Group

1. A Medical Device Coordination Group ('MDCG') is hereby established.

2. Each Member State shall appoint to the MDCG, for a three-year term which may be renewed, one member and one alternate each with expertise in the field of medical devices, and one member and one alternate with expertise in the field of *in vitro* diagnostic medical devices. A Member State may choose to appoint only one member and one alternate, each with expertise in both fields.

The members of the MDCG shall be chosen for their competence and experience in the field of medical devices and *in vitro* diagnostic medical devices. They shall represent the competent authorities of the Member States. The names and affiliation of members shall be made public by the Commission.

Information, documentation, updates

MDCG page

https://ec.europa.eu/health/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_it

Main site Medical Devices EU

https://ec.europa.eu/health/medical-devices-sector/overview_en

Competent Authorities for Medical Devices CAMD

https://www.camd-europe.eu

European Association of Notified bodies for Medical devices (Team-NB)

https://www.team-nb.org

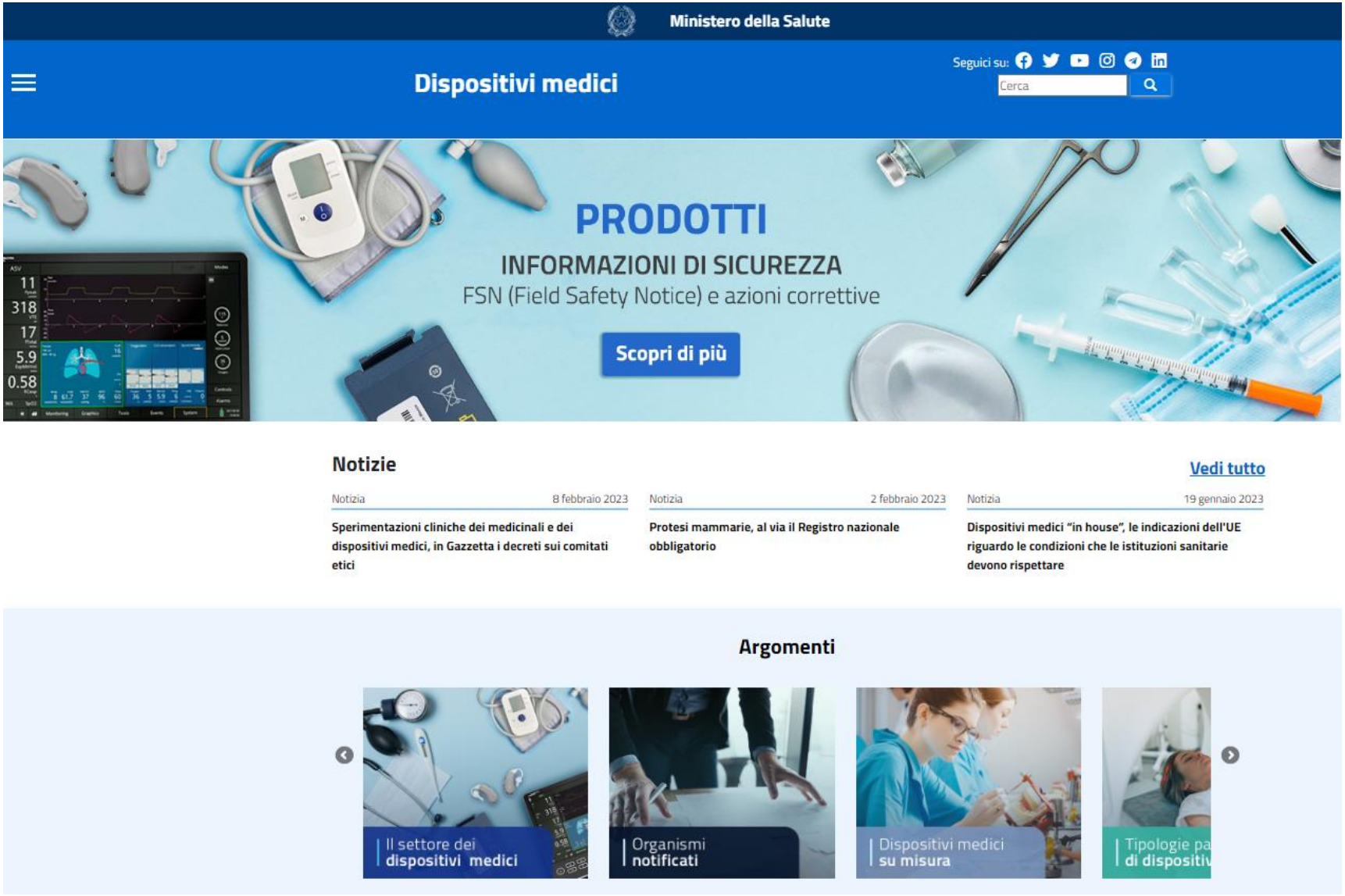
IMDRF - GHTF

http://www.imdrf.org/ghtf/ghtf-archives.asp

NANDO

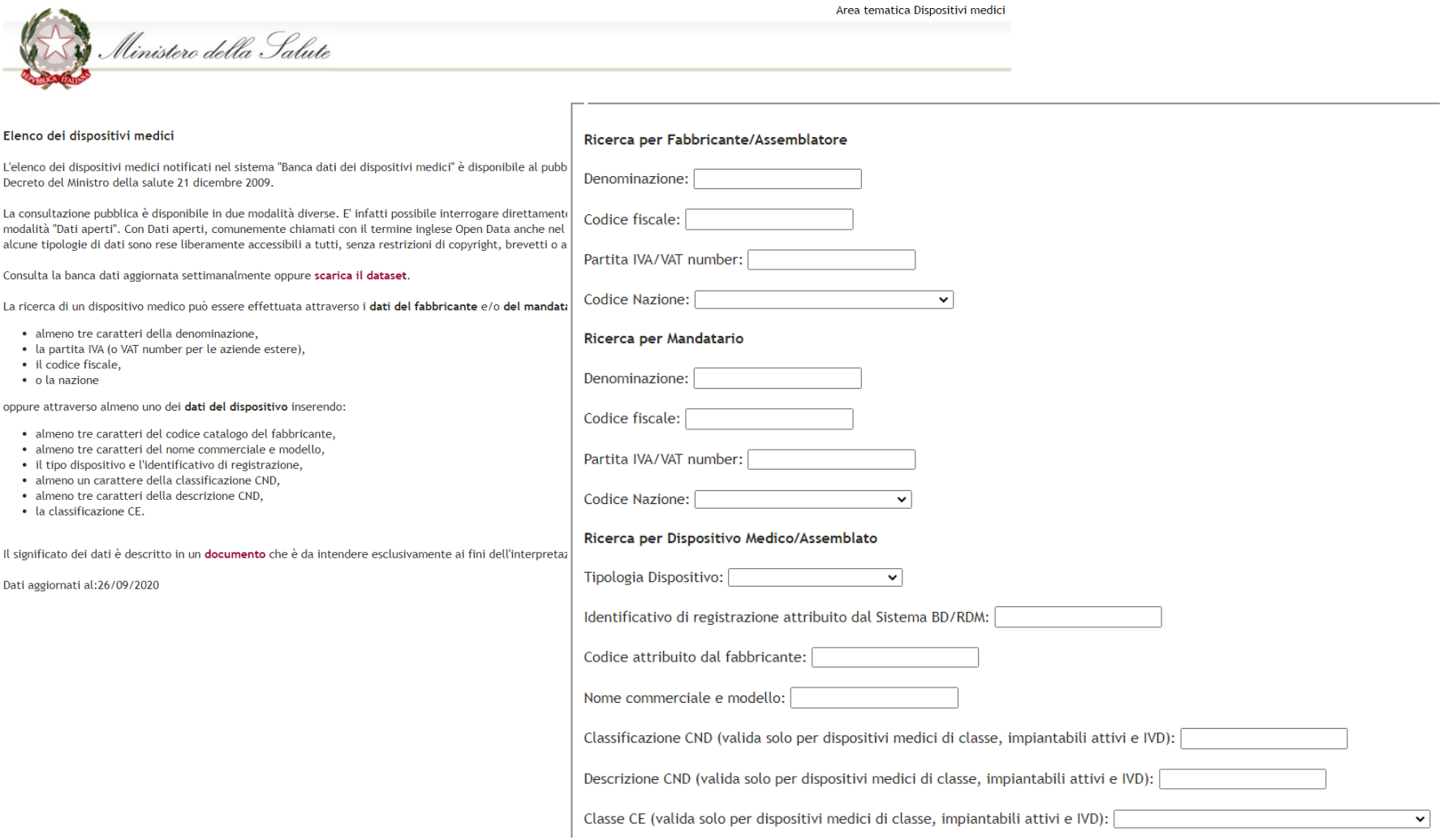
https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.main

Informazioni, documentazione, aggiornamenti



https://www.salute.gov.it/portale/dispositiviMedici/homeDispositiviMedici.jsp

Informazioni, documentazione, aggiornamenti



Area tematica Dispositivi medici

Ministero della Salute

Elenco dei dispositivi medici

L'elenco dei dispositivi medici notificati nel sistema "Banca dati dei dispositivi medici" è disponibile al pubb
Decreto del Ministro della salute 21 dicembre 2009.

La consultazione pubblica è disponibile in due modalità diverse. E' infatti possibile interrogare direttament
modalità "Dati aperti". Con Dati aperti, comunemente chiamati con il termine inglese Open Data anche nel
alcune tipologie di dati sono rese liberamente accessibili a tutti, senza restrizioni di copyright, brevetti o a

Consulta la banca dati aggiornata settimanalmente oppure **scarica il dataset**.

La ricerca di un dispositivo medico può essere effettuata attraverso i **dati del fabbricante** e/o **del mandat**

- almeno tre caratteri della denominazione,
- la partita IVA (o VAT number per le aziende estere),
- il codice fiscale,
- o la nazione

oppure attraverso almeno uno dei **dati del dispositivo** inserendo:

- almeno tre caratteri del codice catalogo del fabbricante,
- almeno tre caratteri del nome commerciale e modello,
- il tipo dispositivo e l'identificativo di registrazione,
- almeno un carattere della classificazione CND,
- almeno tre caratteri della descrizione CND,
- la classificazione CE.

Il significato dei dati è descritto in un **documento** che è da intendere esclusivamente ai fini dell'interpreta

Dati aggiornati al:26/09/2020

Ricerca per Fabbricante/Assemblatore

Denominazione:

Codice fiscale:

Partita IVA/VAT number:

Codice Nazione:

Ricerca per Mandatario

Denominazione:

Codice fiscale:

Partita IVA/VAT number:

Codice Nazione:

Ricerca per Dispositivo Medico/Assemblato

Tipologia Dispositivo:

Identificativo di registrazione attribuito dal Sistema BD/RDM:

Codice attribuito dal fabbricante:

Nome commerciale e modello:

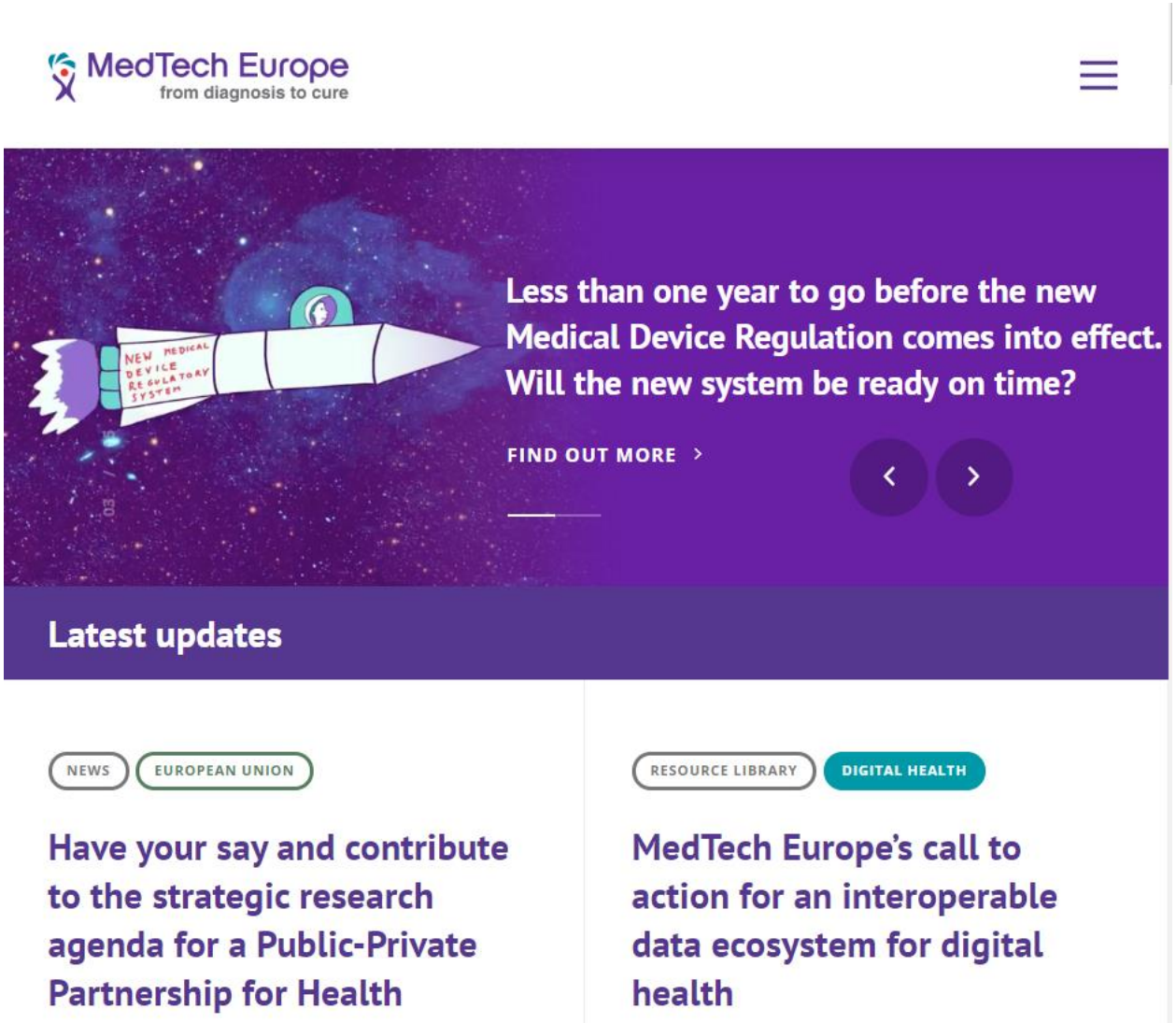
Classificazione CND (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Descrizione CND (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

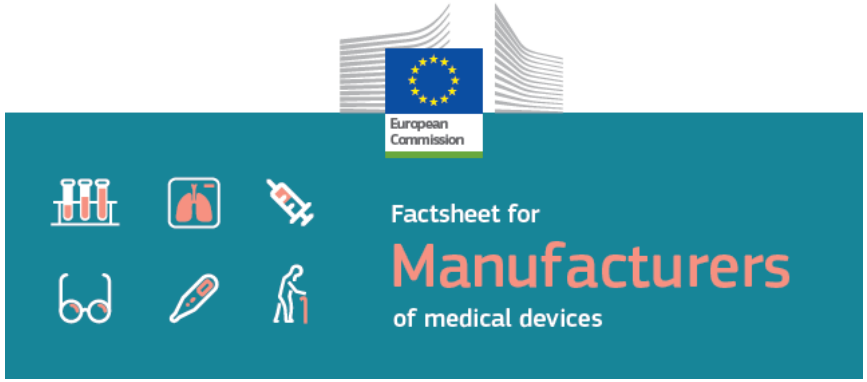
http://www.salute.gov.it/interrogazioneDispositivi/RicercaDispositiviServlet?action=ACTION_MASCHERA

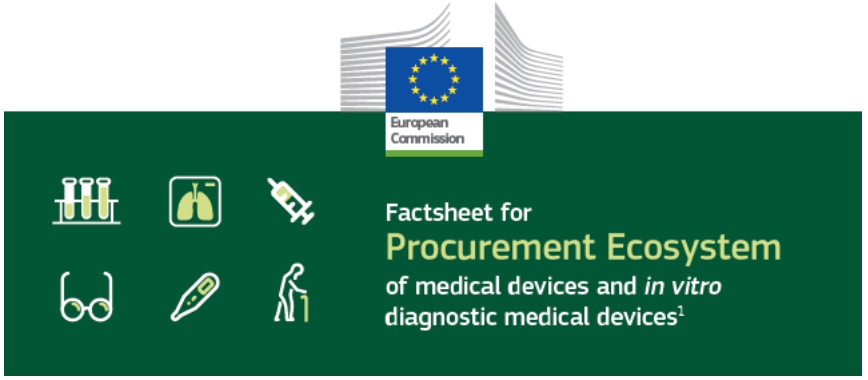
Information, documentation, updates



https://www.medtecheurope.org

Factsheets





https://ec.europa.eu/health/medical-devices-sector/publications_en

European Commission

Implementation Model for medical devices Regulation

Step by Step Guide

MEDICAL DEVICES CHANGE OF LEGISLATION
What you need to know!

STEP	INTENTION / ACTION
1 Pre-assessment	Brief management to ensure a clear understanding of the importance and business implications of the MDR
	Consider organisational challenges: management awareness, staffing capability and availability, budget implications
2 Gap analysis and actions resulting from this	Assess impact on products, internal resources, organisation and budget
	Check new classification rules (MDR Classes I, IIa, IIb and III) and confirm conformity assessment routes for existing and future products
	Check the new definition of MD, particularly with respect to its expanded scope. This also applies to products covered in Annex XVI
	Review the changes needed to existing technical documentation (Technical Files)
	Review and upgrade quality management system (QMS) (point 3 below)
	Check the adequacy of available clinical evidence and risk management and identify any gaps (Article 61)
	Review product labelling (Annex I Chapter III)
	Ensure post-market surveillance (PMS) arrangements are adequate (Chapter VII Section 1)
	Prepare a post-market clinical follow-up plan (PMCF, Annex XIV Part B)
	Get ready for the new vigilance requirements (Chapter VII Section 2)
	Ensure the respect of traceability obligations (Chapter III)
3 Quality Management System (QMS)	Review adequacy of QMS to meet standards and processes for medical devices under the new Regulation
	Build new regulatory requirements into the QMS
	Identify/hire the person(s) responsible for regulatory compliance within your organisation (Article 15) and be sure they are adequately qualified and trained.
4 Legal entities	Clarify how the company is affected: legal entities, obligation of economic operators, organisational structures and resources
	Consider organisational challenges: management awareness, staffing capability and availability, budget implications
	Ensure product liability insurance is adequate
5 Portfolio	Do a cost/benefit analysis for your product portfolio; bear in mind costs for the possible upgrade of risk class of MDs and for the new procedures for conformity assessment as well as the costs for post-market surveillance and gaps in the technical documentation, and plan your transition to the MDR accordingly
	Review supply chain provisions, and clarify roles and responsibilities of business partners (authorised representatives, importers, distributors)
6 Master implementation plan	Build a roadmap for implementation, including definition of sub-projects, resource requirements and a steering group, and ensure overall responsibility for MDR implementation has been established
	Give special consideration to certificate expiry dates, bearing in mind the transitional period, transitional provisions and availability of your Notified Bodies
7 Notified Bodies	Contact the selected Notified Bodies and determine their capacity and availability to service the implementation plan
8 Regulatory training	Empower and train staff through MDR implementation and transition workshops
9 Execute master implementation plan	Implement the various sub-projects (clinical evaluation, technical documentation, relation with other economic operators, Unique Device Identification, labelling, registration, post-market surveillance, vigilance, and reporting IT systems)
	Ensure a cross-functional project management team is in place to cover all aspects of implementation
	Ensure overall and individual responsibilities for MDR implementation have been established
10 Review efficiency and effectiveness	Implement regular meetings on project status and progress, discrepancy and gap analyses, risks, next steps and requirements
	Hold regular progress reviews against the MDR implementation plan and include these in the management review process
11 Notified Body submission	Discuss submission dates to avoid delays in the approval process
12 Ongoing monitoring	Actively monitor the still-developing European regulatory environment and guidelines expected in the coming months (check *European Commission* page on medical devices and subscribe to the newsletter)
	Establish a procedure for dealing with unannounced inspections from Notified Bodies
	Regularly review the MDR implementation plan, identifying and addressing key areas of risk

Health

ET-03-18-102-EN-N

01/08/2020

https://ec.europa.eu/health/md_newregulations/overview_en

Funded under the Third EU Health Programme

ISBN: 978-92-79-89634-7 DOI: 10.2873/614436

European Commission

Factsheet for Manufacturers of medical devices

This Factsheet is aimed at manufacturers of medical devices. For a general overview of the impact of the in vitro diagnostic medical devices Regulation (IVDR) on manufacturers see the Factsheet for manufacturers of in vitro diagnostic medical devices. References to Annexes and Articles in this factsheet refer to the MDR (2017/745/EU).

The new medical devices Regulation (2017/745/EU) (MDR) and the *in vitro* diagnostic medical devices Regulation (2017/746/EU) (IVDR) bring EU legislation into line with technical advances, changes in medical science, and progress in law making.

The new Regulations create a robust, transparent, and sustainable regulatory framework, recognised internationally, that improves clinical safety and creates fair market access for manufacturers.

In contrast to Directives, Regulations do not need to be transposed into national law. The MDR and the IVDR will therefore reduce the risks of discrepancies in interpretation across the EU market.

Transitional periods are planned to smooth the application of the new Regulations. However, you should bear in mind that consultants, in-house professionals, and Notified Bodies will all get busier as the deadline draws closer.

Act now to be ready on time!

MEDICAL DEVICES CHANGE OF LEGISLATION

What you need to know!

Medical devices Regulation (MDR) background

The MDR will replace the existing medical devices Directive (93/42/EEC) (MDD) and the active implantable medical devices Directive (90/385/EEC) (AIMDD). The MDR was published in May 2017, marking the start of a four year period of transition from the MDD and the AIMDD.

During the transitional period the MDR will come into force gradually, starting with the provisions related to the designation of Notified Bodies and the ability of manufacturers to apply for new certificates under the MDR.

The transitional period will end on 26 May 2021, the "Date of Application" (DoA) of the Regulation. From that date the MDR will apply fully.

What has changed? Main points …

- Risk classification of devices and scope of the Regulations
- Clinical investigations (MDR Articles 62 to 82) and performance studies (IVDR Articles 57 to 77)
- Obligations and regulatory requirements of economic operators[6]
- CE marking of conformity (MDR Article 20 and IVDR Article 18)
- Traceability
- Identification
- EUDAMED database
- Labelling and instructions for use
- Carcinogenic, mutagenic or reprotoxic (CMR) substances and endocrine disruptors
- In-house devices
- Custom-made devices
- Nanomaterials
- Reprocessing of single-use medical devices

THE NEW DEFINITION OF MEDICAL DEVICE AND THE NEW SCOPE OF THE REGULATION

The definition of Medical Device

«medical device»: means 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 of the following **specific medical purposes**:

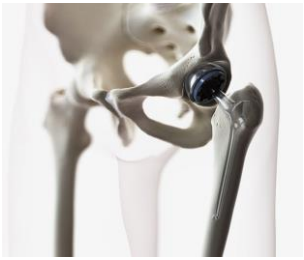
- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

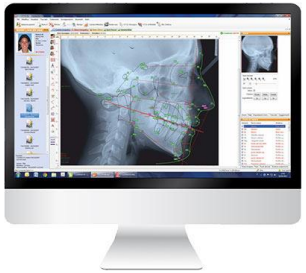
and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

Examples of Medical Devices





… and many more!

Article 1 – Subject matter and scope

1. This Regulation lays down rules concerning the placing on the market, making available on the market or putting into service of medical devices for human use and accessories for such devices in the Union. This Regulation also applies to clinical investigations concerning such medical devices and accessories conducted in the Union.

2. This Regulation shall also apply, as from the date of application of common specifications adopted pursuant to Article 9, to the groups of products without an intended medical purpose that are listed in Annex XVI, taking into account the state of the art, and in particular existing harmonised standards for analogous devices with a medical purpose, based on similar technology. The common specifications for each of the groups of products listed in Annex XVI shall address, at least, application of risk management as set out in Annex I for the group of products in question and, where necessary, clinical evaluation regarding safety.

Inclusion of product without an intended medical purpose

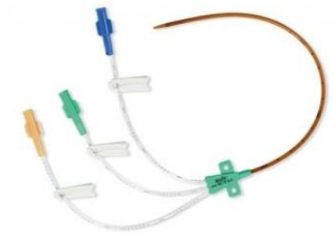
ANNEX XVI - LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE REFERRED TO IN ARTICLE 1(2)

1. Contact lenses or other items intended to be introduced into or onto the eye.
2. Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
3. Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.
4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
5. High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.
6. Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

Article 1 – Subject matter and scope

8. Any device which, when placed on the market or put into service, **incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product** as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in point 10 of Article 1 of that Directive, **and that has an action ancillary to that of the device**, shall be assessed and authorised in accordance with this Regulation.

However, **if the action of that substance is principal and not ancillary to that of the device**, the integral product shall be governed by Directive 2001/83/EC or Regulation (EC) No 726/2004 of the European Parliament and of the Council (1), as applicable. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the device part are concerned.



Catheter coated with anticoagulant:
Medical Device 2017/745

Medicated plaster: **drug**

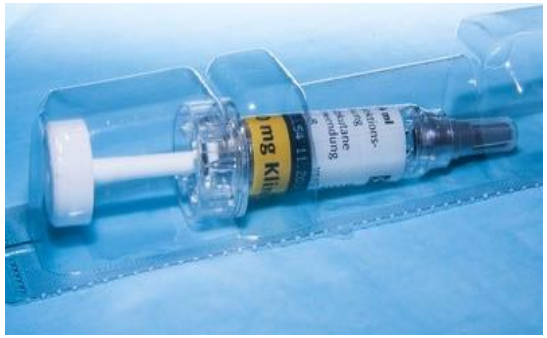
Article 1 – Subject matter and scope

9. Any device which is **intended to administer a medicinal product** as defined in point 2 of Article 1 of Directive 2001/83/EC shall be governed by this Regulation, without prejudice to the provisions of that Directive and of Regulation (EC) No 726/2004 with regard to the medicinal product.

However, if the device intended to administer a medicinal product and the medicinal product are placed on the market in such a way that **they form a single integral product which is intended exclusively for use in the given combination and which is not reusable**, that single integral product shall be governed by Directive 2001/83/EC or Regulation (EC) No 726/2004, as applicable. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the device part of the single integral product are concerned.

Syringe pump: **Medical Device 2017/745**

Syringe for injections: **Medical Device 2017/745**



Syringe for heparin administration: **drug**

THE TRANSITION PERIOD

L 80/24 EN Official Journal of the European Union 20.3.2023

REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 March 2023

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices

(Text with EEA relevance)

Big news!!

Relevant definitions

Definitions …. to keep in mind!!!

«placing on the market» means the first making available of a device, other than an investigational device, on the Union market;

«making available on the market» means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

«putting into service» means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

An important note from The 'Blue Guide' on the implementation of EU products rules 2022

2.3. Placing on the market

— *A product is placed on the market when it is made available for the first time on the Union market. According to Union harmonisation legislation, each individual product can only be placed once on the Union market.*

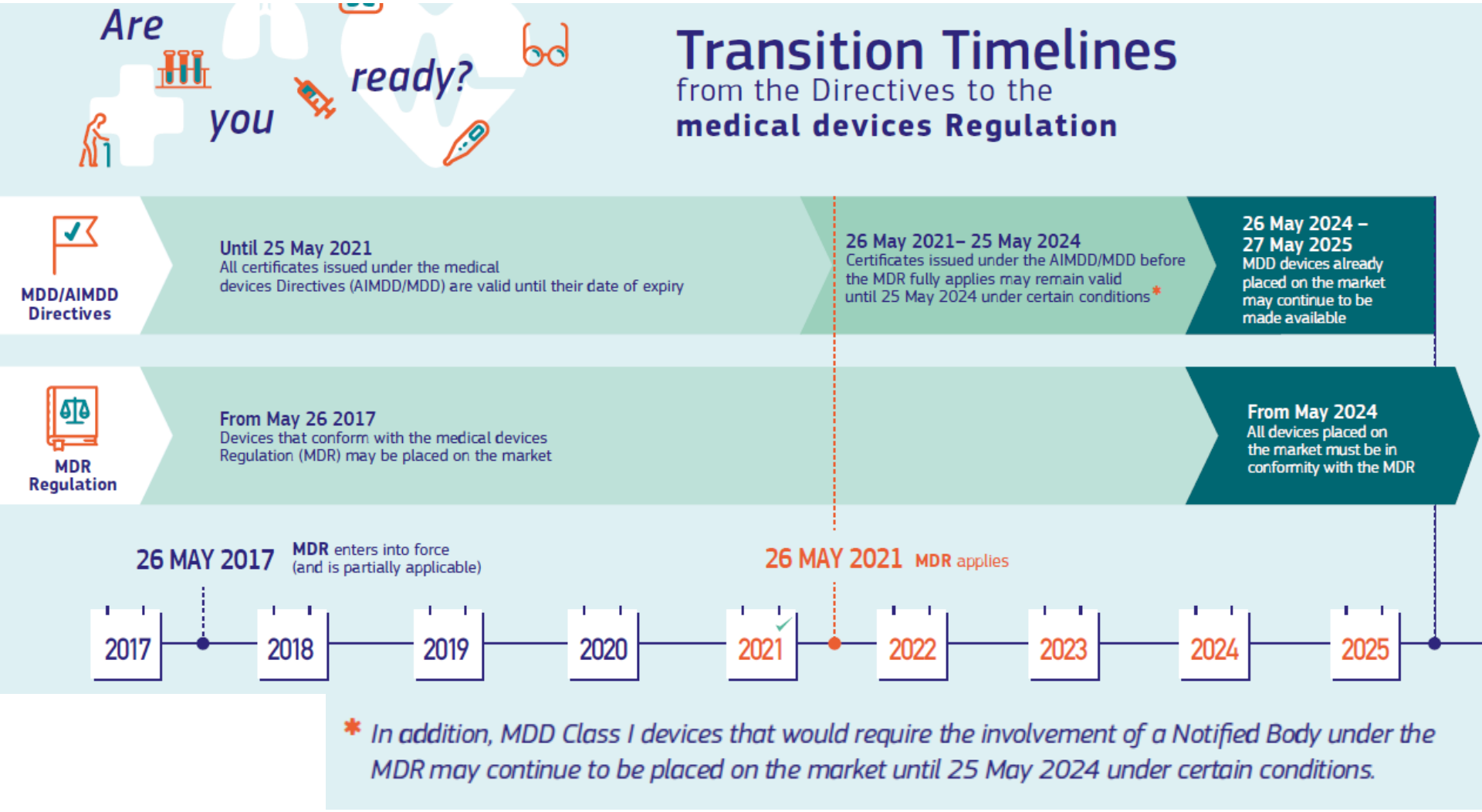
— *Products made available on the market must comply with the applicable Union harmonisation legislation at the moment of placing on the market.*

For the purposes of Union harmonisation legislation, a product is placed on the market when it is made available for the first time on the Union market. This operation should be done by the manufacturer or by an importer ([46]). When a manufacturer or an importer supplies a product to a distributor ([47]) or an end-user for the first time, the operation is always labelled in legal terms as 'placing on the market'. Any subsequent operation, for instance, from a distributor to distributor or from a distributor to an end-user is defined as making available.

As for 'making available', the concept of placing on the market refers to each individual product, not to a type of product, and whether it was manufactured as an individual unit or in series. Consequently, placing on the Union market can only happen once for each individual product across the EU and does not take place in each Member State. Even though a product model or type has been supplied before new Union harmonisation legislation laying down new mandatory requirements entered into force, individual units of the same model or type, which are placed on the market after the new requirements have become applicable, must comply with these new requirements.

Placing a product on the market requires an offer or an agreement (written or verbal) between two or more legal or natural persons for the transfer of ownership, possession or any other property right concerning the product in question; it requires that the manufacturing stage has been completed. This transfer could be for payment or free of charge. It does not require the physical handover of the product. Sometimes products are manufactured following the placing of an order. An offer or agreement concluded before the stage of manufacture has been finalised cannot be considered as placing on the market (e.g. an offer to manufacture a product according to certain specifications agreed by the parties to the contract, where the product will only be manufactured and delivered at a later stage).

MDR transition timelines
Art. 120 Transitional provisions (OLD VERSION!!!)



MDR transition timelines
Art. 120 Transitional provisions

1. From 26 May 2021, any publication of a notification in respect of a notified body in accordance with Directives 90/385/EEC and 93/42/EEC shall become void..

2. Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to 25 May 2017 shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 to Directive 90/385/EEC or Annex IV to Directive 93/42/EEC which shall become void at the latest on 27 May 2022.

Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024.

3. By way of derogation from Article 5 of this Regulation, a device which is a class I device pursuant to Directive 93/42/EEC, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, or which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article, may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2021 it continues to comply with either of those Directives, **and provided there are no significant changes in the design and intended purpose**. **However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives**.

Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in the first subparagraph shall continue to be responsible for the appropriate surveillance in respect of all of the applicable requirements relating to the devices it has certified.

MDR transition timelines
Art. 120 Transitional provisions

4. Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2021, and devices placed on the market from 26 May 2021 pursuant to paragraph 3 of this Article, may continue to be made available on the market or put into service until 26 May 2025.

5. By way of derogation from Directives 90/385/EEC and 93/42/EEC, devices which comply with this Regulation may be placed on the market prior to 26 May 2021.

6. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified prior to 26 May 2021. Notified bodies which are designated and notified in accordance with this Regulation may carry out the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation prior to 26 May 2021.

NB: The «grace period» defined in Art. 120 is valid only for Devices with a valid MDD certificate released from a Notified Body (Class Is, Im, IIa, IIb, III) and for Class I MDD devices that change Class under the new rules of MDR.

Need for a further delay!

Brussels, 6.1.2023
COM(2023) 10 final

2023/0005 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices

REGOLAMENTO (UE) 2023/607 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO

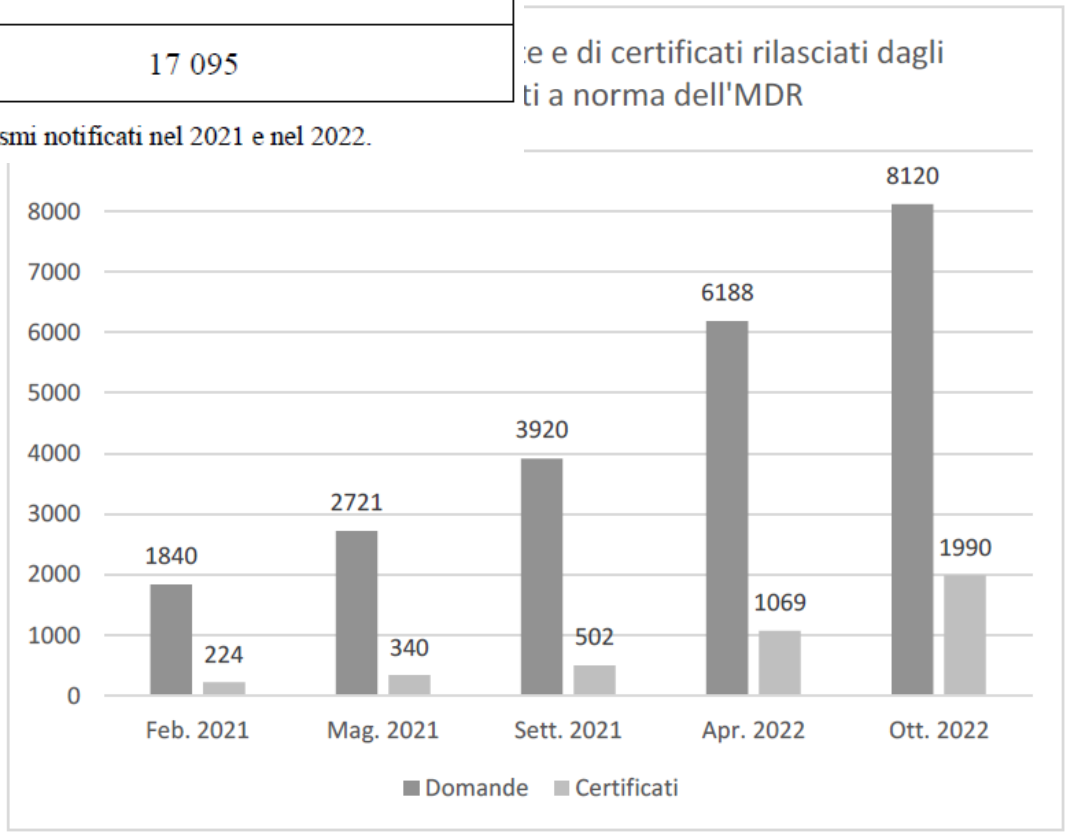
del 15 marzo 2023

che modifica i regolamenti (UE) 2017/745 e (UE) 2017/746 per quanto riguarda le disposizioni transitorie per determinati dispositivi medici e dispositivi medico-diagnostici in vitro

Need for a further delay!

Anno di scadenza	Numero di certificati scaduti/in scadenza rilasciati a norma delle direttive 90/385/CEE e 93/42/CEE del Consiglio
2021 (dal 26 maggio)	1 139
2022	2 370
2023	4 311
2024 (fino al 26 maggio 2024)	17 095

Fonte: Commissione europea, sulla base dei dati forniti dagli organismi notificati nel 2021 e nel 2022.



Fonte: Commissione europea, sulla base dei dati forniti nell'ottobre 2022 da 30 organismi notificati.

The new transition rules

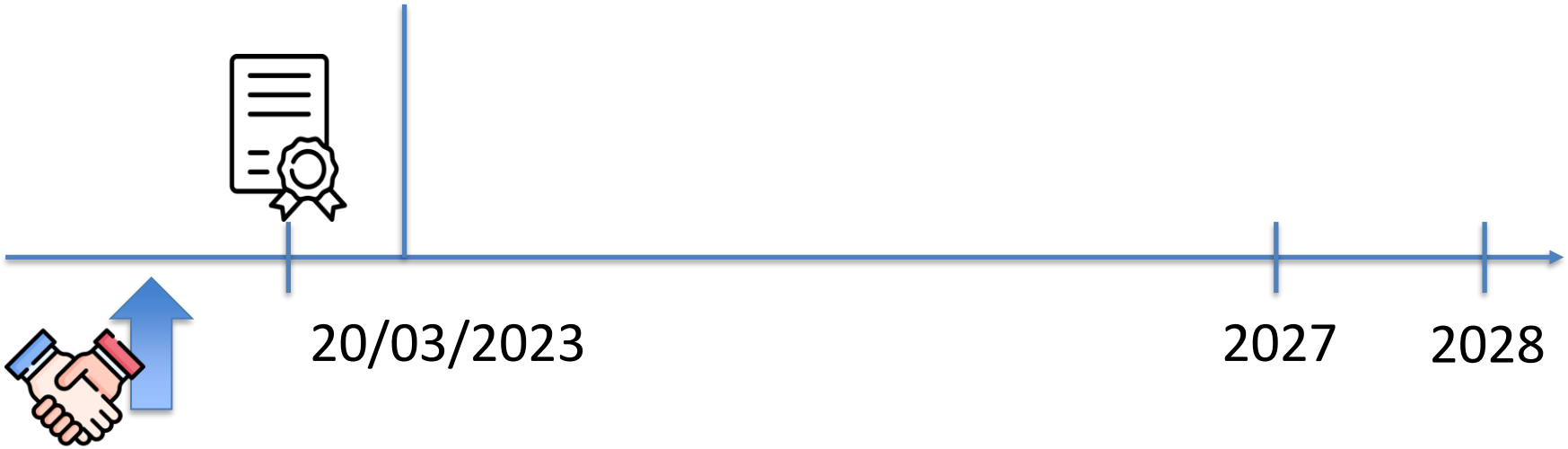
The new text of the Art. 120 MDR becomes extremely complex (if it wasn't already complex enough before!!!)

In summary …

- The end date of the transitional period for PLACING ON THE MARKET has been **moved from 05/25/2024 to 12/31/2027 (for Class III and IIb implantables) and to 12/31/2028 (for Class I, IIa and i IIb non-implantable)**
- **The end date of the transitional period for MAKING AVAILABLE ON THE MARKET (which was 27/05/2025) is removed**
- This possibility is subject to **certain conditions** (signing of a contract with a notified body for the transition to MDR, quality management system, absence of significant modifications, etc.)

The new transition rules

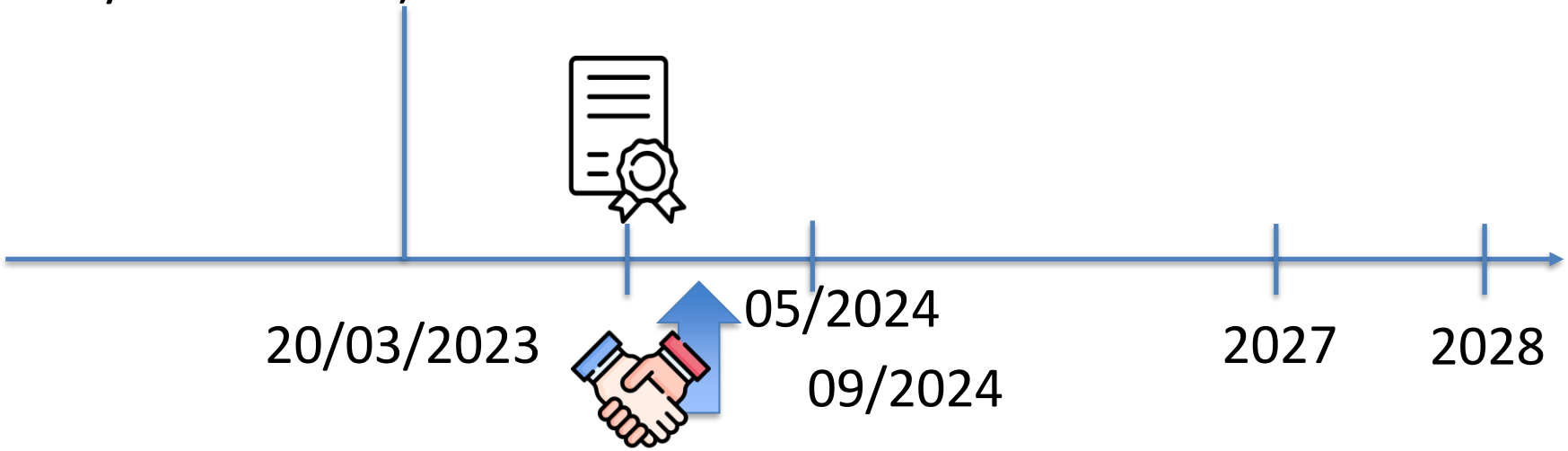
Case 1: certificate already expired on the date of entry into force of the new extension regulation (20/03/2023)



- The extension applies only if the company had already signed the contract with the notified body before the expiry of the certificate

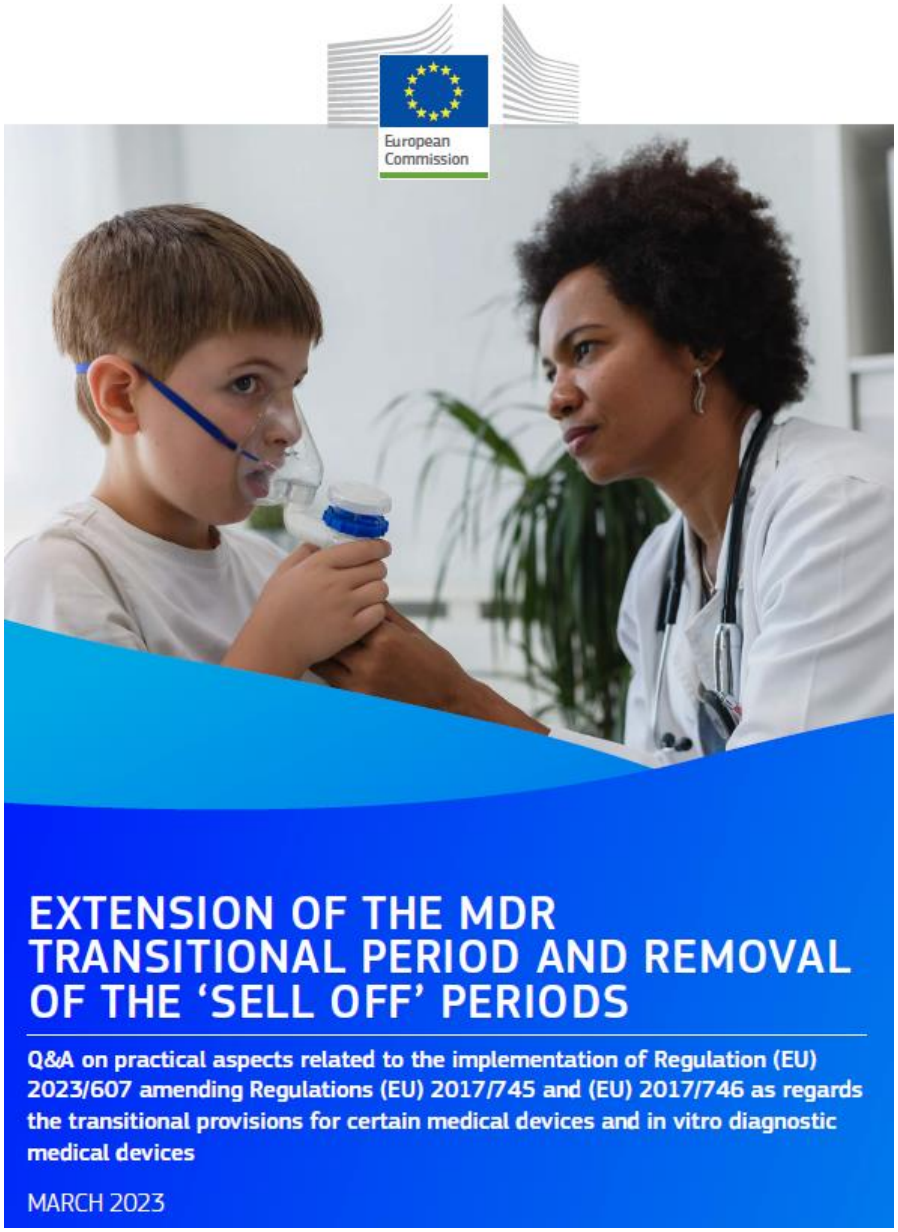
The new transition rules

Case 2: certificate that has not expired on the date of entry into force of the new extension regulation (20/03/2023) and which expires in the following months (by May 2024), or Class I MDD (like many medical sw)



- The extension applies only if the company submits an application to a notified body by 05/26/2024 and signs the contract by 09/26/2024

The new transition rules



The new transition rules

7. How can the manufacturer demonstrate that its legacy device benefits from the extension of the transitional period?

The extension of the transitional period and the concomitant extension of the certificate's validity is done automatically by law, provided the conditions laid down in Article 120(3c) MDR are fulfilled. In case of devices for which the relevant certificate has expired before 20 March 2023, also the conditions laid in the second subparagraph of Article 120(2), points (a) or (b), MDR need to be fulfilled (see below part C).

In line with MDCG guidance 2020-3[4], during the transitional period, notified bodies cannot issue new MDD/AIMDD certificates. However, they can provide written confirmation correcting or complementing information on an existing certificate.

It is acknowledged that the manufacturer may need to demonstrate validity of the certificate to third parties, for example to access the market in third countries or to submit tenders in procurement procedures. For that purpose, manufacturers should have access to different means of demonstrating that their device is covered by the extended transitional period and a valid certificate.

The manufacturer should be able to provide a self-declaration confirming that the conditions for the extension are fulfilled, stating the end date of the transition period. Such self-declaration could be based on a harmonised template. Such self-declaration should clearly identify the devices covered by the extension and certificates concerned. Additional evidence could be provided by a 'confirmation letter' issued by the notified body stating the receipt of the manufacturer's application for conformity assessment and the conclusion of a written agreement. Such confirmation should clearly identify the devices covered by the extension and certificates concerned. Such confirmation letter could be based on a harmonised template and be issued, in principle, without extra costs.

Competent authorities should be able to issue certificates of free sale for the duration of the extended certificate validity.

The European Commission will update its factsheets for competent authorities in non-EU/EEA countries, for healthcare professionals and healthcare institutions and for the procurement ecosystem, explaining the functioning of the extended transition period.

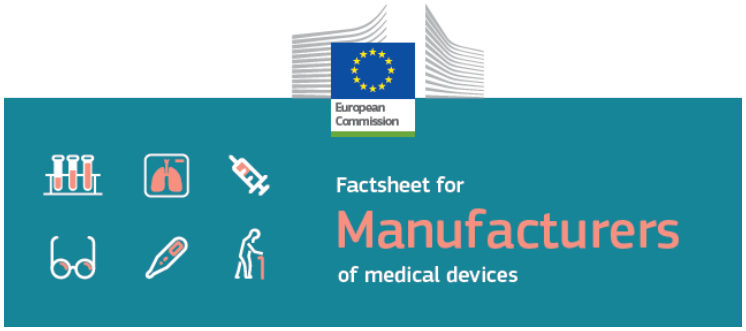
PART E – DELETION OF THE 'SELL-OFF' DATE

18. Which devices will benefit from the removal of the 'sell-off' date?

In Article 120(4) MDR and in Article 110(4) IVDR, the deadline for the further making available on the market of devices placed on the market in accordance with the previously applicable Directives has been deleted. That means that medical devices that have been placed on the market prior to 26 May 2021 in accordance with the MDD/AIMDD or after 26 May 2021 during the transitional period provided for in Article 120 MDR (i.e. until 31 December 2027 or 31 December 2028, as applicable) may continue to be made available on the market or put into service without any limitation in time without prejudice to the device's possible shelf-life or expiry date.

The same applies to in vitro diagnostic medical devices that have been placed on the market prior to 26 May 2022 in accordance with the IVDD or after 26 May 2022 during the transitional period provided for in Article 110 IVDR (i.e. until 26 May 2025, 26 May 2026 or 26 May 2027, as applicable). Those IVD may continue to be made available on the market or put into service without any limitation in time without prejudice to the device's possible shelf-life or expiry date.

… no discrimination!



To avoid market disruption and allow a smooth transition from the Directives to the Regulation, several transitional provisions are in place (Article 120). Some devices with certificates issued under the Directives (AIMDD/MDD certificates) may continue to be placed on the market until 26 May 2024[1], and made available until 26 May 2025[2].

During the transition phase, products certified under the Directives and products certified under the Regulation will coexist on the market. Both will have equal status under the law, and no discrimination on eligibility criteria in public tenders may take place.

CLOSING REMARKS

MAIN CRITICALITIES

- **MANY RULES ARE TOO COMPLEX AND UNCLEAR** (even for the subjects that should «make the system work» … Competent Authorities and Notified Bodies)
- **REDUCED NUMBER OF NOTIFIED BODIES** (an issue for the renewal of certifications)
- **LONG TIMES FOR THE NEW CERTIFICATIONS AND BIG COSTS INCREASE** (impact on the availability of products, legacy and new … technological innovation?)
- **THE NEW RULES ARE PENALIZING THE ECONOMIC OPERATORS** (especially small and medium enterprises)
- **EUDAMED IS NOT YET FULLY WORKING** (it would be the fundamental database to make the MDR fully operative)

IS THERE A REAL RISK OF SHORTAGE OF MEDICAL DEVICES IN EUROPE?

- MDR certificates have not been issued yet for >85% of the >500,000 devices previously certified under the MDD or AIMDD.
- The time-to-certification with MDR-designated Notified Bodies is taking 13-18 months on average. This is double the time historically needed for certification under the Directives.
- 54% of survey respondents said that they do not intend to transition some of their portfolio to the MDR. All product categories are impacted by potential device discontinuations.
- Small and Medium Enterprises (SMEs) face more challenges in MDR implementation than larger companies. At least 15 % and up to 30% of SMEs still have no access to an MDR-designated Notified Body. For SMEs progress to MDR certification is slower than average.
- MDR is currently a disincentive against launching medical device innovation in the EU: approximately 50% of respondents are deprioritising the EU market (or will do so) as the geography of choice for first regulatory approval of their new devices.

TAKEAWAY MESSAGES

- The European framework on Medical Devices is evolving in the direction of stricter rules and increased attention to safety and quality
- Implementation criticalities of the new Medical Device Regulations are a concern for all stakeholders
- The management of medical devices inside hospitals is of paramount importance for patient safety and quality of care
- Proper maintenance is a key tool for high quality management of medical devices

… AND MORE IS YET TO COME …

IMDRF International Medical Device Regulators Forum

Artificial Intelligence Medical Devices

Develop an aligned approach to the management of artificial intelligence based medical devices.

Software as a Medical Device

Promote consistency in regulatory assessment for Software as a Medical Device to reach patients more efficiently.

Medical Device Cybersecurity Guide

Manage cybersecurity risks in medical devices through a life-cycle approach. Striking the right balance between pre-market and post-market requirements.

Personalized Medical Devices (PMD)

Harmonize the regulatory requirements for medical devices that are intended for a particular individual, considering unique characteristics and risks associated with each type of device.

Dipartimento di Ingegneria e Architettura

CEI CENTRAL EUROPEAN INITIATIVE

BioingTS

Thank you for the attention!

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UNIVERSITÀ DEGLI STUDI DI TRIESTE

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AIIC associazione italiana ingegneri clinici