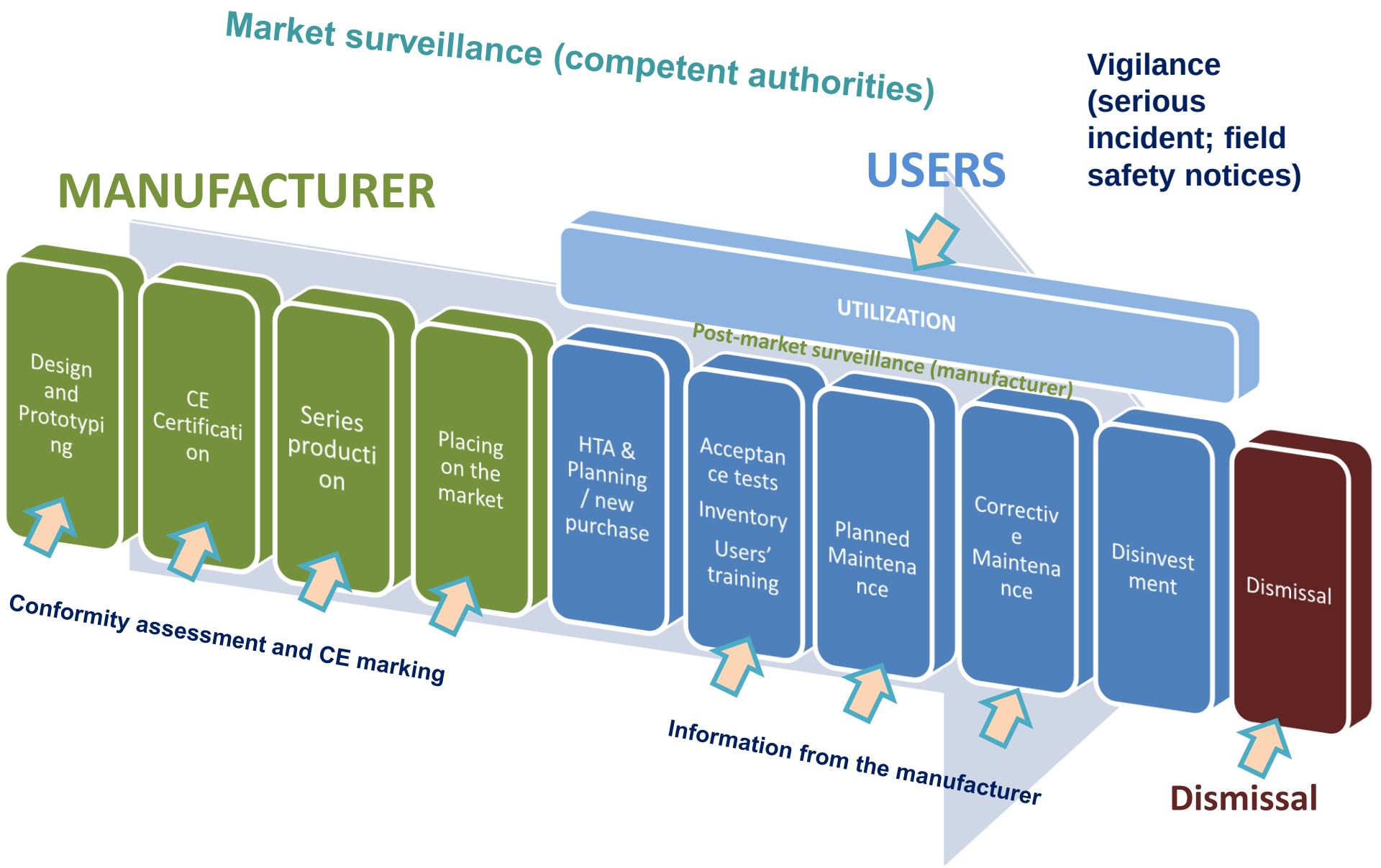
New European Regulations, MDR and IVDR

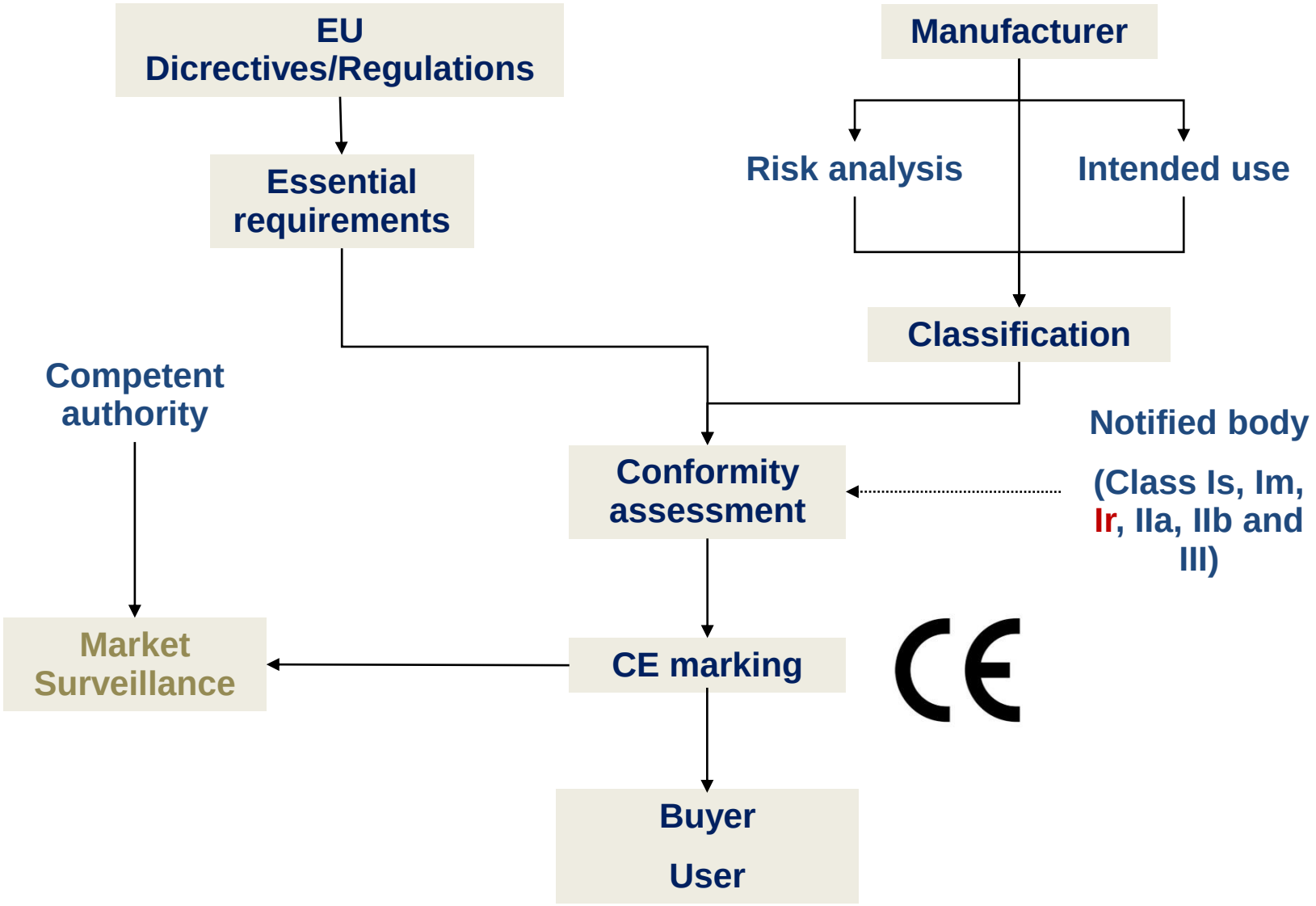
Ing. Stefano Bergamasco
MedTech Projects Srl
stefano.bergamasco@medtechprojects.com

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

«Life cycle» of medical technologies



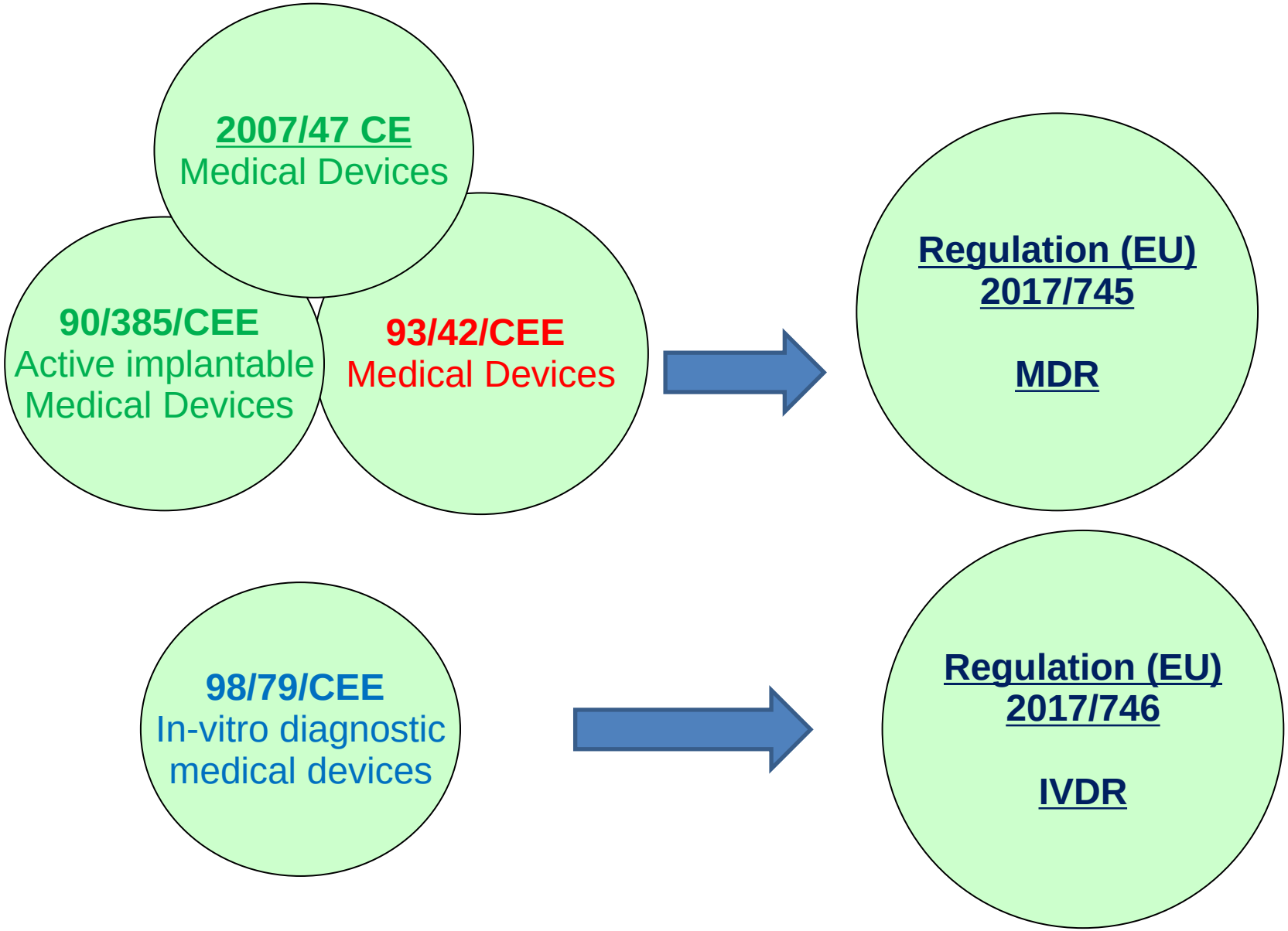
Main context



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

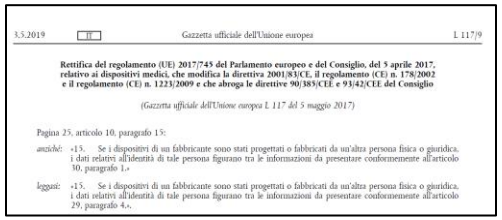
I

(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

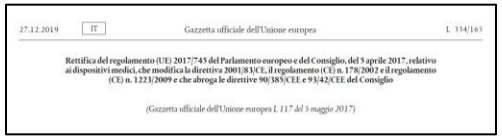
(Gazzetta ufficiale dell'Unione europea L 117 del 5 maggio 2017)

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)

WHERE YOU CAN FIND INFORMATION ADN UPDATES

EN English Search

Public Health

European Commission > Public Health > Medical Devices - Sector > Overview

Overview

PAGE CONTENTS

Medical devices and In Vitro Diagnostic medical devices (IVDs) have a fundamental role in saving lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.

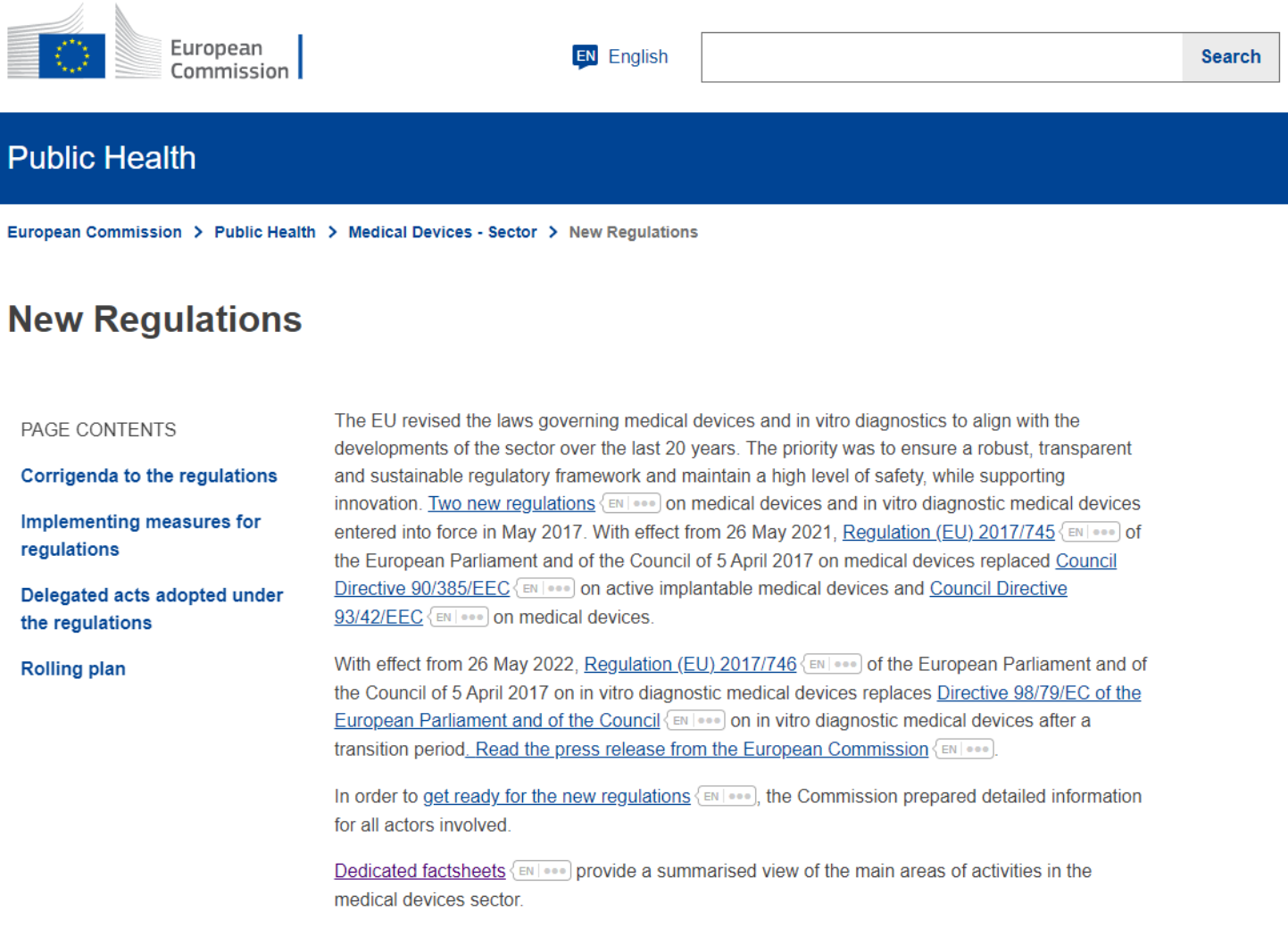
The EU has a competitive and innovative medical devices sector, characterised by the active role of small and medium-sized enterprises. It is supported by a regulatory framework that aims to ensure the smooth functioning of the internal market, taking as a base a high level of protection of health for patients and users.

There are over 500 000 types of medical devices and IVDs on the EU market. Examples of medical devices are sticking plasters, contact lenses, X-ray machines, pacemakers, breast implants, software apps and hip replacements. IVDs are used to perform tests on samples, and examples include HIV blood tests, pregnancy tests and blood sugar monitoring systems for diabetics.

The medical devices sector is essential to the provision of healthcare to citizens and is an important player in both the European and global economy.

- Legislation EN

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



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

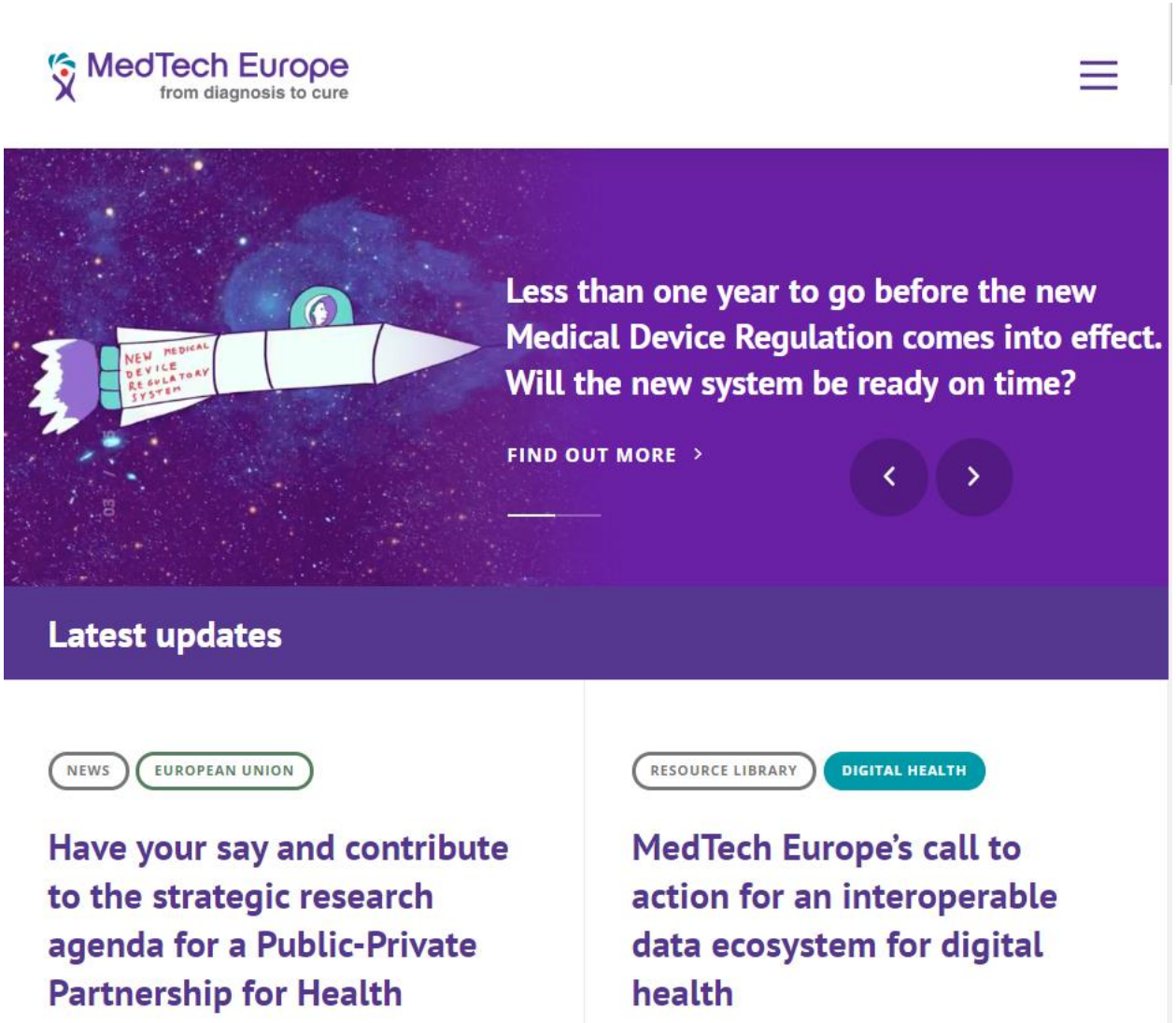
IMDRF - GHTF

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

NANDO

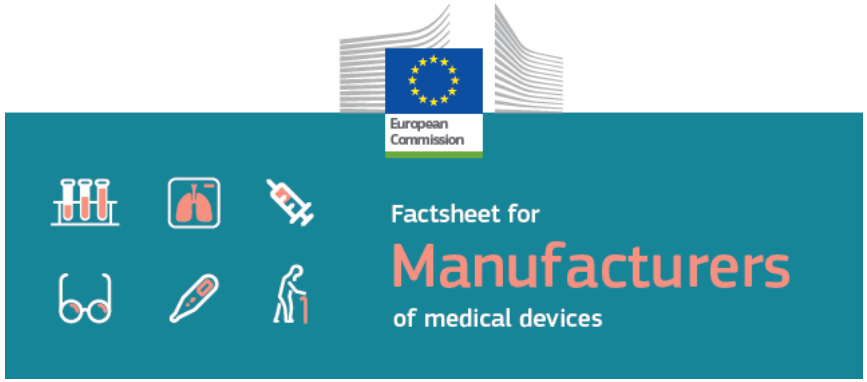
https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.main

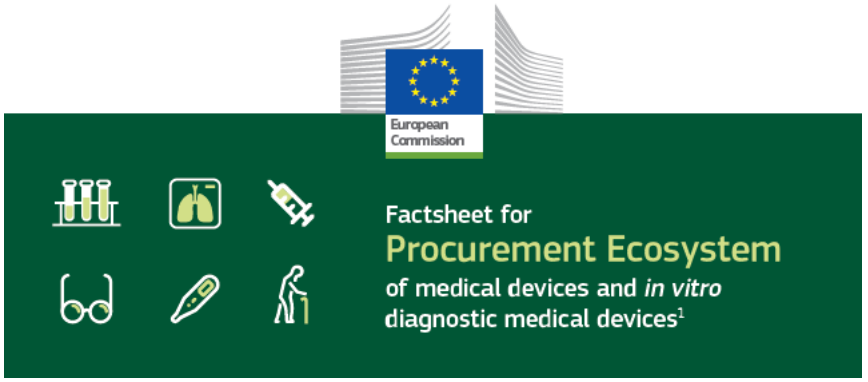
Information, documentation, updates



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:

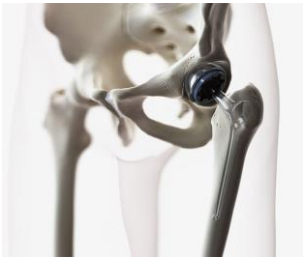
- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process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

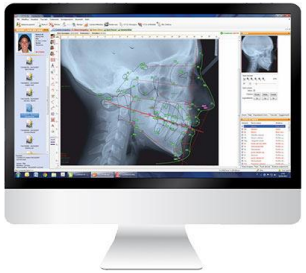
and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

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

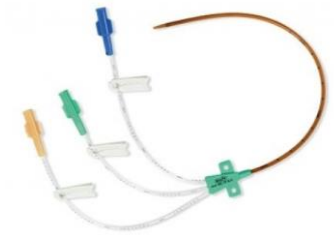
ANNEX XVI - LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE REFERRED TO IN ARTICLE 1(2)

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**

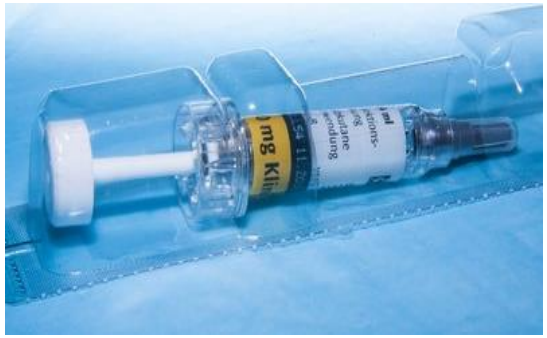
Article 1 – Subject matter and scope

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:

The move to May 26, 2021 of the date of application of the MDR and consequences on the transition period, the validity of the declarations of conformity and EC certificates

The «problem» of Notified Bodies

56 Notified Bodies under MDD 93/42

Body type	Name	Country
NB 2265	3EC International a.s.	Slovakia
NB 0318	AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS	Spain
NB 0086	BSI Assurance UK Ltd	United Kingdom
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 1370	BUREAU VERITAS ITALIA S.P.A.	Italy
NB 0633	Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH	Germany
NB 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.	Hungary
NB 0546	CERTIQUALITY S.R.L. - ISTITUTO DI CERTIFICAZIONE DELLA QUALITA'	Italy
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 0297	DQS Medizinprodukte GmbH	Germany
NB 2282	DQS Polska Sp. z o.o	Turkey
NB 1014	ELEKTROTECHNICKÝ ZKUŠEBNÍ U	Poland
NB 1282	ENTE CERTIFICAZIONE MACCHIN	Denmark
NB 0537	Eurofins Expert Services Oy	Sweden
NB 0681	Eurofins Product Service GmbH	Belgium
NB 0477	Eurofins Product Testing Italy S.r.	Finland
NB 2803	G.F.I. Health Technology Certifica	United Kingdom
NB 0459	GMED	Germany
NB 0425	ICIM S.P.A.	Slovenia
NB 0051	IMQ ISTITUTO ITALIANO DEL MA	Switzerland **(MRA)**
NB 1023	INSTITUT PRO TESTOVÁNI A CER	Turkey
NB 0413	INTERTEK SEMKO AB	Australia **(MRA)**
NB 0373	ISTITUTO SUPERIORE DI SANITA	Turkey
NB 0426	ITALCERT SRL	Italy
NB 0476	KIWA CERMET ITALIA S.P.A.	Germany
NB 1984	Kiwa Belgelendirme Hizmetleri A.	Germany
NB 0483	MDC MEDICAL DEVICE CERTIFIC	Germany
NB 0482	MEDCERT ZERTIFIZIERUNGS- UN	Germany
NB 0068	MTIC InterCert S.r.l.	Germany
NB 0653	NATIONAL EVALUATION CENTER EKAPTY	Turkey
NB 1011	NEOEMKI Nemzeti Orvostechnika Felelősségű Társaság (NEOEMKI	Slovakia
NB 0050	National Standards Authority of I	Slovakia
NB 2764	Notice Belgelendirme, Muayene ve Denetim Hizmetleri Anonim Şirketi	Turkey
NB 1434	POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.	Poland
NB 0543	Presafe Denmark A/S	Denmark
NB 0402	RISE Research Institutes of Sweden AB	Sweden
NB 1639	SGS Belgium NV	Belgium
NB 0598 (ex-0403)	SGS FIMKO OY	Finland
NB 0120	SGS United Kingdom Limited	United Kingdom
NB 0494	SLG PRÜF UND ZERTIFIZIERUNGS GMBH	Germany
NB 1304	SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - SIQ	Slovenia
NB 1250	Schweizerische Vereinigung für Qualitäts- und Managementsysteme	Switzerland **(MRA)**
NB 2195	Szutest Uygunluk Değerlendirme A.Ş.	Turkey
NB 0805	THERAPEUTIC GOODS ADMINISTRATION	Australia **(MRA)**
NB 1783	TURKISH STANDARDS INSTITUTION (TSE)	Turkey
NB 2274	TUV NORD Polska Sp. z o.o	Poland
NB 1936	TUV Rheinland Italia SRL	Italy
NB 0044	TÜV NORD CERT GmbH	Germany
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany
NB 2292	UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş.	Turkey
NB 2854	bqs. s.r.o.	Slovakia
NB 0481	ecm-Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH	Germany

MedTech Projects

UNIVERSITÀ DEGLI STUDI DI TRIESTE

The «problem» of Notified Bodies

Body type	Name	Country
NB 2265	3EC International a.s.	Slovakia
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 1370	BUREAU VERITAS ITALIA S.P.A.	Italy
NB 0633	Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH	Germany
NB 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.	Hungary
NB 0318	CENTRO NACIONAL DE CERTIFICACION DE PRODUCTOS SANITARIOS	Spain
NB 0546	CERTIQUALITY S.r.l.	Italy
NB 0344	DEKRA Certification B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany
NB 2460	DNV Product Assurance AS	Norway
NB 0297	DQS Medizinprodukte GmbH	Germany
NB 0537	Eurofins Electric & Electronics Finland Oy	Finland
NB 0477	Eurofins Product Testing Italy S.r.l.	Italy
NB 0459	GMED SAS	France
NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy
NB 0373	ISTITUTO SUPERIORE DI SANITA'	Italy
NB 0426	ITALCERT SRL	Italy
NB 2862	Intertek Medical Notified Body AB	Sweden
NB 0476	KIWA CERMET ITALIA S.P.A.	Italy
NB 1912	Kiwa Dare B.V.	Netherlands
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 1434	POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.	Poland
NB 1639	SGS Belgium NV	Belgium
NB 0598 (ex-0403)	SGS FIMKO OY	Finland
NB 1304	SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - SIQ	Slovenia
NB 2274	TUV NORD Polska Sp. z o.o	Poland
NB 1936	TUV Rheinland Italia SRL	Italy
NB 0044	TÜV NORD CERT GmbH	Germany
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH	Germany
NB 2696	UDEM Adriatic d.o.o.	Croatia

33 Notified Bodies under MDR 2017/745

Body type	Name	Country
NB 2265	3EC International a.s.	Slovakia
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 0344	DEKRA Certification B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany
NB 0459	GMED SAS	France
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH	Germany

7 Notified Bodies under IVDR 2017/746

Updated 28th September 2022

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.*

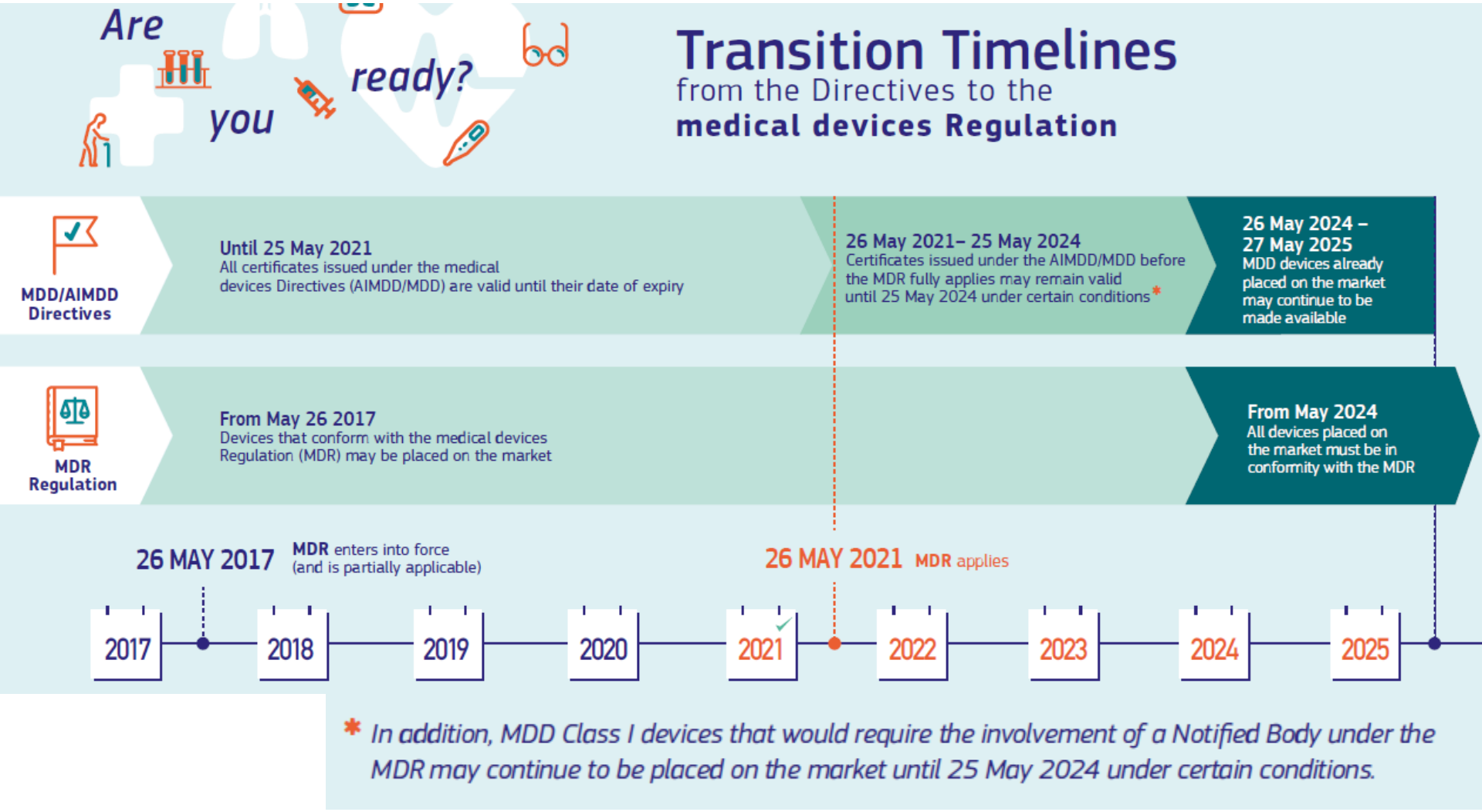
— *Products made available on the market must comply with the applicable Union harmonisation legislation at the moment of placing on the market.*

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



* *In addition, MDD Class I devices that would require the involvement of a Notified Body under the MDR may continue to be placed on the market until 25 May 2024 under certain conditions.*

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

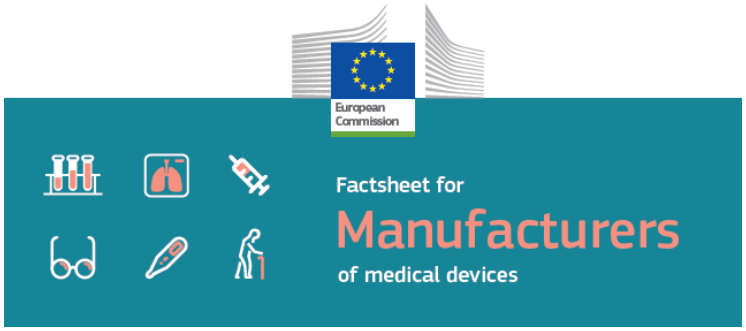
4. Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2021, and devices placed on the market from 26 May 2021 pursuant to paragraph 3 of this Article, may continue to be made available on the market or put into service until 26 May 2025.

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.

… 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.

THE NEW OBLIGATIONS OF THE MANUFACTURER OF MEDICAL DEVICES

Definition of manufacturer

Manufacturer *means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;*

Article 16

Cases in which obligations of manufacturers apply to importers, distributors or other persons

1. A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if it does any of the following:

(a) makes available on the market a device under its name, registered trade name or registered trade mark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation;

(b) changes the intended purpose of a device already placed on the market or put into service;

(c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

Other economic operators

*(32) **'authorised representative'** means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;*

Art. 11-12

*(33) **'importer'** means any natural or legal person established within the Union that places a device from a third country on the Union market;*

Art. 13

*(34) **'distributor'** means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;*

Art. 14

*(35) **'economic operator'** means a manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3);*

MDR 2017/745 – Art. 10 General obligations of manufacturers

1. When placing their devices on the market or putting them into service, manufacturers **shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation**.
2. Manufacturers shall **establish, document, implement and maintain a system for risk management** as described in Section 3 of Annex I.
3. Manufacturers shall conduct a **clinical evaluation** in accordance with the requirements set out in Article 61 and Annex XIV, including a PMCF.
4. Manufacturers of devices other than custom-made devices shall draw up and keep up to date technical documentation for those devices. The **technical documentation** shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in **Annexes II and III**. The Commission is empowered to adopt delegated acts in accordance with Article 115 amending, in the light of technical progress, the Annexes II and III.
5. Manufacturers of **custom-made devices** shall draw up, keep up to date and keep available for competent authorities documentation in accordance with Section 2 of Annex XIII.

Obligations of manufacturers

6. Where compliance with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than custom-made or investigational devices, shall **draw up an EU declaration of conformity** in accordance with Article 19, and **affix the CE marking of conformity** in accordance with Article 20.
7. Manufacturers shall comply with the **obligations relating to the UDI system** referred to in Article 27 and with the registration obligations referred to in Articles 29 and 31.
8. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56, available for the competent authorities for a **period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market**. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market..

Upon request by a competent authority, the manufacturer shall, as indicated therein, provide that technical documentation in its entirety or a summary thereof.

A manufacturer with a registered place of business outside the Union shall, in order to allow its authorised representative to fulfil the tasks mentioned in Article 11(3), ensure that the authorised representative has the necessary documentation permanently available.

Obligations of manufacturers

9. Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in device design or characteristics and changes in the harmonised standards or CS by reference to which the conformity of a device is declared shall be adequately taken into account in a timely manner. **Manufacturers of devices, other than investigational devices, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device**.

The quality management system shall cover all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation.

The quality management system shall address at least the following aspects:

…..

Obligations of manufacturers

(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;

(b) identification of applicable general safety and performance requirements and exploration of options to address those requirements;

(c) responsibility of the management;

(d) resource management, including selection and control of suppliers and sub-contractors;

(e) risk management as set out in in Section 3 of Annex I;

(f) clinical evaluation in accordance with Article 61 and Annex XIV, including PMCF;

(g) product realisation, including planning, design, development, production and service provision;

(h) verification of the UDI assignments made in accordance with Article 27(3) to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 29;

(i) setting-up, implementation and maintenance of a post-market surveillance system, in accordance with Article 83;

(j) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;

(k) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;

(l) management of corrective and preventive actions and verification of their effectiveness;

(m) processes for monitoring and measurement of output, data analysis and product improvement.

Obligations of manufacturers

10. Manufacturers of devices shall implement and keep up to date the **post-market surveillance system** in accordance with Article 83.
11. Manufacturers shall ensure that the device is **accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient**. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.
12. Manufacturers who consider or have reason to believe that a device which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary **corrective action to bring that device into conformity, to withdraw it or to recall it**, as appropriate. They shall inform the distributors of the device in question and, where applicable, the authorised representative and importers accordingly. Where the device presents a serious risk, manufacturers shall immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 56, in particular, of the non-compliance and of any corrective action taken.
13. Manufacturers shall have a **system for recording and reporting of incidents and field safety corrective actions** as described in Articles 87 and 88.

Obblighi dei fabbricanti

14. Manufacturers shall, upon request by a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language determined by the Member State concerned. The competent authority of the Member State in which the manufacturer has its registered place of business may require that the manufacturer provide samples of the device free of charge or, where that is impracticable, grant access to the device. **Manufacturers shall cooperate with a competent authority, at its request, on any corrective action** taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market or put into service.

…..

15. Where manufacturers have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 30(1).
16. Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law.

Manufacturers shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have **measures in place to provide sufficient financial coverage in respect of their potential liability** under Directive 85/374/EEC, without prejudice to more protective measures under national law.

PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE

Person responsible for regulatory compliance

Article 15

1. Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices. The requisite expertise shall be demonstrated by either of the following qualifications:

a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Without prejudice to national provisions regarding professional qualifications, manufacturers of **custom-made devices** may demonstrate the requisite expertise referred to in the first subparagraph by having at least **two years of professional experience within a relevant field of manufacturing**.

Person responsible for regulatory compliance

2. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC (1) shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal.

(1) <50 employees and revenues <=10M€

Person responsible for regulatory compliance

3. The person responsible for regulatory compliance shall at least be responsible for ensuring that:

a) **the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;**

b) **the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;**

c) **the post-market surveillance obligations are complied with in accordance with Article 10(10);**

d) **the reporting obligations referred to in Articles 87 to 91 are fulfilled;**

e) **in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV is issued**

4. If a number of persons are jointly responsible for regulatory compliance in accordance with paragraphs 1, 2 and 3, their respective areas of responsibility shall be stipulated in writing.

Person responsible for regulatory compliance

5. The person responsible for regulatory compliance shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his or her duties, regardless of whether or not they are employees of the organisation.

6. Authorised representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union. The requisite expertise shall be demonstrated by either of the following qualifications:

a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

QUALIFICATION: IS MY PRODUCT A MEDICAL DEVICE IN THE FIRST PLACE?

FOCUS on SaMD/MDSW

Guidance on Qualification and Classification of Software

Medical Device

Medical Device Coordination Group Document MDCG 2019-11

MDCG 2019-11

Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR

October 2019

Guidance on Qualification and Classification of Software

Qualification of Software as a Medical Device

Software must have a medical purpose on its own to be qualified as a medical device software (MDSW). It should be noted that the intended purpose as described by the manufacturer of the software is relevant for the qualification and classification of any device.

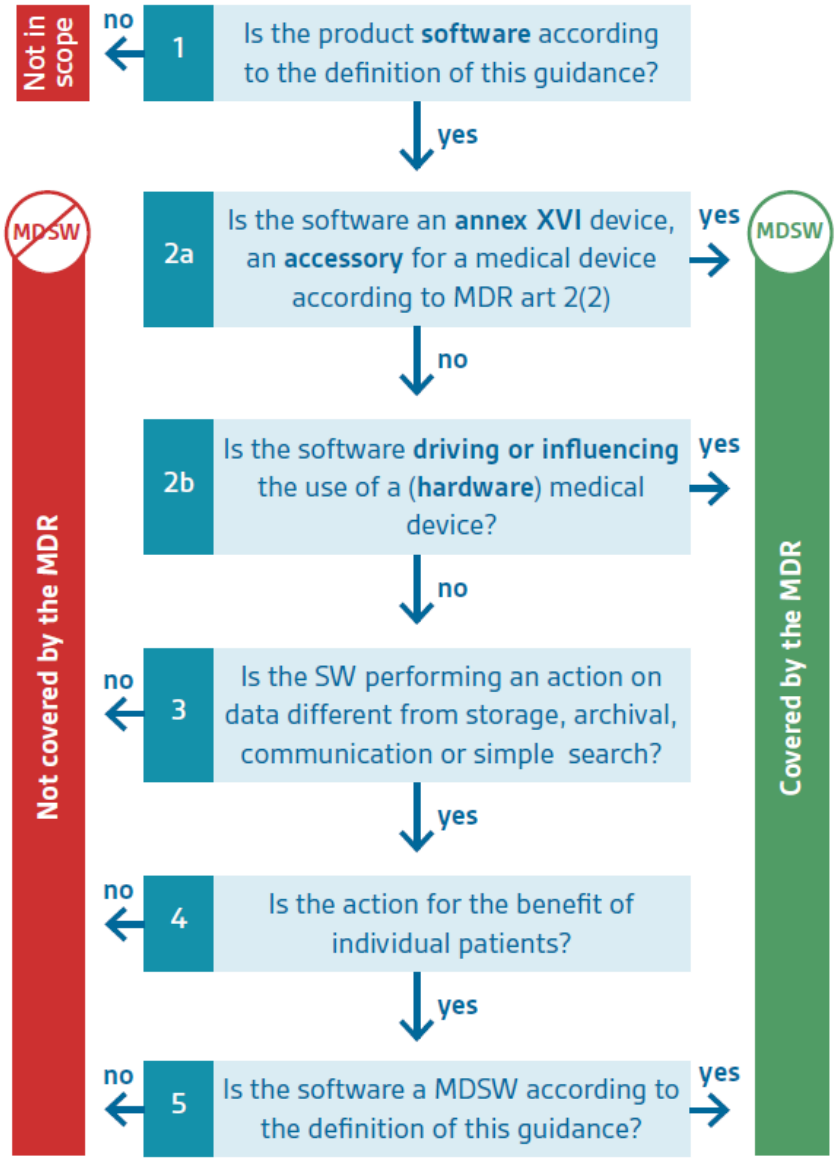
In order to be qualified as medical device software, the product must first fulfil the definition of software according to this guidance and the definition of a medical device according to Article 2(1) of Regulation (EU) 2017/745 – MDR.

It is important to clarify that not all software used within healthcare is qualified as a medical device. For example, “Simple search”, which refers to the retrieval of records by matching record metadata against record search criteria or to the retrieval of information does not qualify as medical device software (e.g. library functions).

However, software which is intended to **process, analyse, create or modify medical information may be qualified as a medical device software** if the creation or modification of that information is governed by a medical intended purpose.

Software intended for non-medical purposes (excluding MDR Annex XVI devices), such as invoicing or staff planning, does not qualify as a medical device software. These software do not fall under the Medical Devices Regulations.

It must be highlighted that the risk of harm to patients, users of the software, or any other person, related to the use of the software within healthcare, including a possible malfunction is not a criterion on whether the software qualifies as a medical device.



1. Look if the Software matches the Software definition:
   A set of instructions that processes input data and creates output data.
2. a) Look if the Software matches the Accessory definition (MDR art 2(2)): *An article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s).*
   The part or the accessory can be individually CE marked.
   b) Look if the Software is driving or influencing hardware. If the software is part of hardware, then classification rule 11 does not apply as it then falls within the same risk class as the device (MDR Annex VIII implementing rule 3.2).
3. Look if the Software matches 3.
4. Look if the Software matches 4:
   *) Software for population and epidemiological studies is not in scope.
   *) Software for educational purposes is not in scope, provided it is not directed at individual patients, i.e. doesn't use patient input data to provide patient specific decision support.
5. Look if the Software matches the MDSW definition.
   Software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a "medical device" in the Medical Devices Regulation.

   In other words: does the software create information for a medical purpose?
   *) regardless of its location: e.g. operating in the cloud, on a computer, on a mobile phone, or as an additional functionality on a hardware medical device.
   *) regardless of whether the software, in addition, also drives or influences the use of a (hard-ware) device.

Guidance on Qualification and Classification of Software

Figure 4 Examples of software modules with intended purpose

No Medical Device Intended Purpose	Software module	Medical Device Intended Purpose
- Patient information transfer or storage	Electronic Patient Record System	- Image viewer with diagnostic functionality - Medication module
- Patient identification - Patient scheduling	Hospital Information System	- Indicating high blood pressure
- Showing and saving pictures	Picture Archive Communication System	- Compare pictures to identify disease progression
- Measuring skin tone to prevent sunburn	Health app	- Measuring skin tone to prevent cancer

NEW CLASSIFICATION RULES IN THE MDR

FOCUS on SaMD/MDSW

Classification rules

The Classification in 4 classes remains as already foreseen by the Directive, but with some important changes in the classification rules

Class III

Class IIb

Class IIa

Class I, Im, Is, Ir

Classification of medical devices

L 117/140 EN Official Journal of the European Union 5.5.2017

ANNEX VIII

CLASSIFICATION RULES

Medical Devices
Medical Device Coordination Group Document MDCG 2021- 24

MDCG 2021-24

Guidance on classification of medical devices

October 2021

ANNEX VIII

22 classification rules

- 1-4 NON-INVASIVE DEVICES
- 5-8 INVASIVE DEVICES
- 9-13 ACTIVE DEVICES
- 14-22 SPECIAL RULES

Most software will fall here …

Classification rules

Rule	Remarks
Rule 1 – 4 Non-invasive devices	These rules are in general for non-invasive hardware devices. These rules have to be considered if the MDSW is part of the hardware, driving or influencing the hardware or an accessory to the hardware.
Rule 5-8: Invasive devices	These rules are in general for invasive hardware devices. These rules have to be considered if the MDSW is part of the hardware, driving or influencing the hardware or an accessory to the hardware.
Rule 9-13: Active (including software)	These rules are for software and hardware devices. Software is defined as an active device.
Rule 10: Diagnosis or monitoring	This rule is about diagnosis or monitoring. These two terms should not be confused. In most cases the physician is doing the diagnosis, and the software only provides the information, which is monitoring.
Rule 11: Software	See paragraph 3.4.3 for an extensive explanation.
Rule 14-22 Special rules	These rules describe specific situations, for which additional classification rules are made. These rules are in general not applicable for MDSW. These rules have to be considered if the MDSW is part of the hardware, driving or influencing the hardware or an accessory to the hardware.

Classification rules – ACTIVE DEVICES

Rule 9

All **active therapeutic devices intended to administer or exchange energy** are classified as class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.

All active devices intended to control or monitor the performance of active therapeutic class IIb devices, or intended directly to influence the performance of such devices are classified as class IIb.

All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.

All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III.

General explanation of the rule

This rule covers many different groups of devices, such as:

electrical equipment used in surgery such as lasers and surgical generators; stimulation devices; devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance; devices intended for controlling, monitoring or directly influencing the performance of active implantable devices.

Active implantable devices are covered by Rule 8.

Classification rules – ACTIVE DEVICES

Rule 10

Active devices intended for diagnosis and monitoring are classified as class IIa:

- if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum, in which case they are classified as class I;
- if they are intended to image in vivo distribution of radiopharmaceuticals; or
- if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified as class IIb..

Active devices **intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology**, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.

General explanation of the rule

This rule covers a whole range equipment in various fields for capture of physiological signals, as well as specifically therapeutic and diagnostic radiology.

Classification rules – ACTIVE DEVICES

Rule 11

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

- death or an irreversible deterioration of a person's state of health, in which case it is in class III; or
- a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

All other software is classified as class I.

General explanation of the rule

Rule 11 describes and categorizes the risk of software based on the combination of the significance of the information provided by the software to the healthcare decision and the healthcare situation or patient's condition.

This rule also distinguishes between MDSW (medical device software) intended to monitor vital and non-vital physiological processes (the sub-rule only applies to software intended for monitoring purposes only).

Software used in conjunction with medical devices(s) which solely record, store or display information would generally not be considered devices (see guidance MDCG 2019-11, section 3.3 for further detail). For example, software analogous to diaries for recording insulin doses would not be considered devices, unless an analysis is performed on the data or the device in some way alters the patients treatment, prescription, doses etc.

Classification rules – ACTIVE DEVICES

Rule 12

All **active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body** are classified as class IIa, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are classified as class IIb.

General explanation of the rule

This rule is intended to primarily cover drug delivery systems and anaesthesia equipment. If the device's intended route of drug delivery is pulmonary, Rule 20 applies.

Rule 13

All other active devices are classified as class I.

Classification rules – SPECIAL RULES

Rule 22

Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.

General explanation of the rule

This rule is intended for therapeutic devices whose intended functionality is dependent to a significant degree on an integrated or incorporated diagnostic function.

Automated or 'closed-loop' therapeutic systems are systems in which relevant biological conditions are automatically monitored (uses feedback from physiological sensors) and is used to adjust a therapy in order to maintain or achieve a particular physiological state. Such devices are normally used in precision medicine and/or personalised therapies for obtaining optimal therapeutic efficacy. This rule covers systems such as autonomic pharmacological (drug-delivery) and neuromodulation systems.

'Integrated or incorporated diagnostic function' means the functionality of a system including a physiological sensors e.g. the AED electrodes/pads using a feedback control to process and record changes in the patient's physiological state to continuously adjust a therapy. The diagnostic function can be physically integrated or a component of an external sub-system.

Classification rules – SPECIAL RULES

Class	Rule 22	Examples
III	Active therapeutic devices with an integrated or incorporated diagnostic function[1] which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.	• Automated external defibrillators (AED) including their pads/electrodes • Semiautomatic external defibrillators • Automated closed loop insulin delivery system • Automated external infusion pumps with integrated sensors to adapt the infusion therapy • Devices in brain-computer interfaces (BCIs) – used for e.g. motor control in severely paralyzed patients • Closed-loop systems for deep brain stimulation (DBS) treatment of various neurological conditions
		• Closed-loop dynamic neurochemical control of therapeutic interventions e.g. target-controlled anaesthesia / infusion systems

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!

Ing. Stefano Bergamasco
MedTech Projects Srl
stefano.bergamasco@medtechprojects.com

MedTech Projects

AIIC associazione italiana ingegneri clinici

IFMBE

UNIVERSITÀ DEGLI STUDI DI TRIESTE

comune di trieste

sihta
SOCIETÀ ITALIANA DI HEALTH TECHNOLOGY ASSESSMENT