



# **COMMUNICATION AND INFORMATION CAMPAIGN ON MEDICAL DEVICES REGULATIONS**

**2018-2021**

**DG GROW**



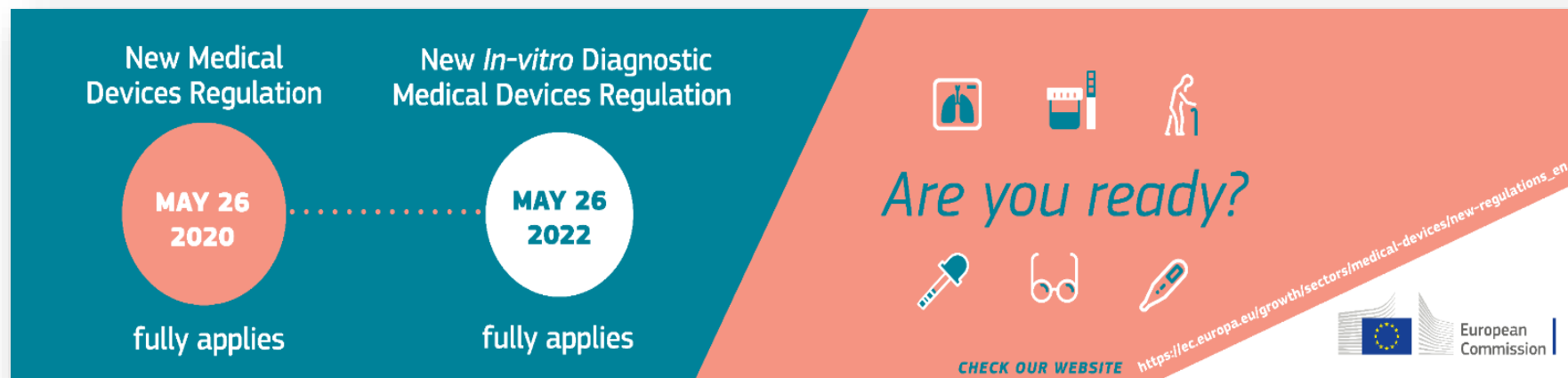
# Introduction

- Objectives of the campaign
- Main tools used/activities performed
- 1st year achievements
- The way ahead: 2<sup>nd</sup> phase of the campaign



# Objectives of the campaign

To raise awareness among stakeholders on the new Regulations and their requirements to avoid disruption of MD and IVD markets





## Main tools used/activities performed

- Website – DG GROW's new page = 'HUB' with key information and relevant links
- Information pack: factsheets and supporting documents for the website and stakeholders' dissemination
- Animated GIFs/visuals for social media campaign
- Infographics, Newsletters, website notifications for stakeholders and subscribers

# Examples

## Website – DG GROW's new page = 'HUB' with key information and relevant links

The screenshot displays a website hub for Medical Devices. On the left is a navigation menu with categories like 'New Regulations', 'Current Directives', and 'Medical devices - links'. The main content area features a 'Medical Devices' header, a descriptive paragraph, a large banner for 'MEDICAL DEVICES IN VITRO DIAGNOSTIC MEDICAL DEVICES GET READY FOR THE NEW REGULATIONS' with icons and a 'What you need to know!' callout, and a 'Highlights' section with a list of links. Below this are 'Newsletter subscription' and 'Get ready' sections. A central article titled 'Getting ready for the new regulations' includes text about EU regulations and a grid of six boxes detailing roles like 'Authorised Representatives, Importers and Distributors' and 'Competent authorities in non-EU/EEA countries'. On the right, a 'Library' section provides a search interface with 'Country' and 'Language' dropdowns and a 'Reset' button.

**Medical Devices**

Medical devices make an essential contribution to healthcare in the EU for the benefit of European citizens. From sticking plasters to X-ray scanners, dentures to hip joints and in-vitro diagnostic devices that monitor diabetes or identify infections; medical devices are crucial in diagnosing, preventing, monitoring and treating illness, and overcoming disabilities. They are also important to the economy, providing €110 billion in sales and 675,000 jobs in Europe. The EU is a net exporter in this sector.

**MEDICAL DEVICES  
IN VITRO DIAGNOSTIC MEDICAL DEVICES  
GET READY FOR THE NEW REGULATIONS**

**What you need to know !**

**Highlights**

- [UDI system frequently asked questions and answers](#)
- [Call for observers of the medical devices coordination group's nomenclature sub-group](#)
- [Call for clinical and other experts to be published later in 2019](#)
- [The Commission designates entities to operate a system for assignment of unique device identifiers \(UDIs\)](#)
- [EUDAMED device data elements' registration timeline](#)
- [EUDAMED legacy devices' registration](#)
- [Further guidance: regulation of medical devices if there's no Brexit deal](#)
- [Using the UKCA marking if the UK leaves the EU without a deal](#)

**Getting ready for the new regulations**

**Regulation (EU) 2017/745 (MDR) and the In-vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) bring EU legislation into line with technical advances, changes in medical science, and progress in**

**create a robust, transparent, and sustainable regulatory framework, recognised by the public, that ensures clinical safety and creates fair market access for manufacturers.**

**These regulations do not need to be transposed into national law. The MDR and the IVDR will therefore apply directly across the EU market.**

of activity?

Manufacturers	Authorised Representatives, Importers and Distributors	Competent authorities in non-EU/EEA countries
Manufacturers IVD	Health institutions reprocessing single-use medical devices	Healthcare professionals and health institutions
Manufacturers MD	Manufacturers of devices without an intended medical purpose	The procurement of MDs and IVDs

**Library**

Comprehensive database of documents produced by stakeholders throughout the European Union, covering in-vitro medical devices, in addition to and to all relevant websites. The Library also covers documents produced by DG GROW related to the Regulations on medical devices and in-vitro medical devices.

Search through our database of external resources by year, country, language and area of activity.

Country:

Language:

[Technical document requirements under MDR - BSI Group](#)

MD, Authorised Representatives, Importers and Distributors, Healthcare professionals

Country: United Kingdom | Language: English

Technical document requirements under the European Medical Device Regulation

[Annex I Requirements \(Annex I ... - BSI Group\)](#)

MD, Authorised Representatives, Importers and Distributors, Healthcare professionals

Country: United Kingdom | Language: English

Comparison between requirements under the MDR and IVDR and the MDD/AIMDD.

MD, Authorised Representatives, Importers and Distributors, Healthcare professionals

# Examples

## Information pack Factsheets and supporting documents

**Factsheet for Manufacturers of *in vitro* Diagnostic Medical Devices**

**MEDICAL DEVICES CHANGE OF LEGISLATION**  
What you need to know!

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 risk 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!**

**In Vitro Diagnostic Medical Devices Regulation (IVDR) background**

The IVDR will replace the existing In Vitro Diagnostic Medical Devices Directive (98/79/EC) (IVDD). The IVDR was published in May 2017, marking the start of a five-year period of transition from the IVDD.

During the transitional period the IVDR 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.

As Directives, Regulations do not need to be transposed into national law. The MDR and the IVDR will therefore reduce the risk 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!**

Internal market, Industry, Entrepreneurship and SMEs

**Factsheet for Manufacturers of Medical Devices**

**MEDICAL DEVICES CHANGE OF LEGISLATION**  
What you need to know!

Manufacturers of medical devices, the impact of the In Vitro Medical Devices Regulation (2017/745/EU) (MDR) and the In Vitro Diagnostic Medical Devices Regulation (2017/746/EU) (IVDR) bring with technical advances, science, and progress in law making.

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 three-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 2020, the "Date of Application" (DoA) of the Regulation. From that date the MDR will apply fully.

**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 three-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 2020, the "Date of Application" (DoA) of the Regulation. From that date the MDR will apply fully.

Internal market, Industry, Entrepreneurship and SMEs

**Factsheet for Procurement Ecosystem of Procurement of Medical Devices and *in vitro* Diagnostic Medical Devices<sup>1</sup>**

**MEDICAL DEVICES CHANGE OF LEGISLATION**  
What you need to know!

The Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR)

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 three-year period of transition from the MDD and the AIMDD.

The IVDR will replace the existing In Vitro Diagnostic Medical Devices Directive (98/79/EC) (IVDD). The IVDR was published in May 2017, marking the start of a five-year period of transition from the IVDD.

Internal market, Industry, Entrepreneurship and SMEs

**Factsheet for Authorised Representatives, Importers and Distributors of Medical Devices and *in vitro* Diagnostic Medical Devices<sup>1</sup>**

**MEDICAL DEVICES CHANGE OF LEGISLATION**  
What you need to know!

Authorised representatives, importers and distributors of medical devices and *in vitro* diagnostic medical devices, the impact of the Medical Devices Regulation (EU) 2017/745 (MDR) and the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) bring with technical advances, science, and progress in law making.

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 three-year period of transition from the MDD and the AIMDD.

The IVDR will replace the existing In Vitro Diagnostic Medical Devices Directive (98/79/EC) (IVDD). The IVDR was published in May 2017, marking the start of a five-year period of transition from the IVDD.

Internal market, Industry, Entrepreneurship and SMEs

**Factsheet for Authorities in non-EU/EEA States on Medical Devices and *in vitro* Diagnostic Medical Devices<sup>1</sup>**

**MEDICAL DEVICES CHANGE OF LEGISLATION**  
What you need to know!

Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR)

As Directives, Regulations do not need to be transposed into national law. The MDR and the IVDR will therefore reduce the risk 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!**


Internal market, Industry, Entrepreneurship and SMEs

<sup>1</sup> The term 'devices' in this document refers to medical devices and *in vitro* diagnostic medical devices. For definitions of what is understood to be a device, see Article 2 of the MDR and the IVDR.


# Examples


## Animated GIFs/visuals for social media

**MEDICAL DEVICES  
CHANGE OF  
LEGISLATION**



**What you  
need to know !**



 European  
Commission



**MEDICAL DEVICES AND  
IN VITRO DIAGNOSTIC  
MEDICAL DEVICES**

**GET READY  
FOR THE NEW  
REGULATIONS**



**Visit our website!**  
[ec.europa.eu/growth/sectors/medical-devices](http://ec.europa.eu/growth/sectors/medical-devices)  
Funded under the Third Health Programme




**MEDICAL DEVICES  
CHANGE OF LEGISLATION**




**WEBSITE  
NOTIFICATIONS**




**The importance of Medical Devices in the EU**



**675,000 jobs**



**+/- €110 billion**



**27,000 companies**  
95%  
SMEs

# Examples

## Infographics

**THE NEW REGULATIONS ON MEDICAL DEVICES AND *IN VITRO* DIAGNOSTIC MEDICAL DEVICES**

Increase clinical investigation requirements and manage risk to ensure patient safety

Reinforce surveillance and management of the entire MD and IVD life cycle

Improve transparency and traceability

Reduce ambiguity with clear classifications and definitions

For more information, visit our website

Funded under the Third Health Programme

**ACT NOW TO BE READY IN TIME**  
Transition Timelines from the Directives to the Regulations

**Medical Devices**

- Until 25 May 2020: All certificates issued under the Medical Devices Directive (MDD) are valid.
- From 26 May 2017: Devices that conform to the Medical Devices Regulation (MDR) may be placed on the market.
- From 26 May 2024: All devices placed on the market must be in conformity with the MDR.

**In vitro Diagnostic Medical Devices**

- Until 25 May 2022: All certificates issued under the *In Vitro* Diagnostic Medical Devices Directive (IVDD) are valid.
- From 26 May 2017: Devices that conform to the *In Vitro* Diagnostic Medical Devices Regulation (IVDR) may be placed on the market.
- From 26 May 2024: All devices placed on the market must be in conformity with the IVDR.

Funded under the Third EU Health Programme

**ACT NOW TO BE READY IN TIME**  
Transition Timelines from the Directives to the Regulations  
Medical Devices and *In vitro* Diagnostic Medical Devices

26 MAY 2017 MDR enters into force

26 MAY 2017 IVDR enters into force

26 MAY 2020 MDR fully applies

26 MAY 2022 IVDR fully applies

26 MAY 2024 All devices placed on the market must conform with the MDR and the IVDR

26 MAY 2025 End of making available devices in conformity with the Directives

All certificates issued under the Directives remain valid, while devices which comply with the Regulations may already start to be placed on the market

Certificates issued under the Directives before the Regulations fully apply may remain valid for up to 2 to 4 additional years

Devices in conformity with the Directives, may continue to be made available

For more information, visit our website

ec.europa.eu/growth/sectors/medical-devices

Funded under the Third Health Programme

**Medical Devices Regulation (MDR) and *In Vitro* Diagnostic Medical Devices Regulation (IVDR)**

The European Commission has adopted 2 new Regulations – the Medical Devices Regulation (MDR) and the *In Vitro* Diagnostic Medical Devices Regulation (IVDR) – to bring EU legislation up to date with medical advances and to ensure better protection of public health and patient safety.

**THE NEW REGULATIONS**

- Increase clinical investigation requirements and manage risk to ensure patient safety
- Reinforce surveillance and management of the entire MD and IVD life cycle
- Improve transparency and traceability
- Reduce ambiguity with clear classifications and definitions

**SOME OF THE NEW FEATURES:**

- Unique Device Identifiers (UDIs)
- European Database on Medical Devices EUDAMED
- An implant card for patients, with information on implanted medical devices
- Stricter pre-market control for high risk devices

Funded under the Third Health Programme



## Website notifications and newsletters



**MEDICAL DEVICES**  
**IN VITRO DIAGNOSTIC MEDICAL DEVICES**  
**GET READY FOR THE NEW REGULATIONS**

**WEB NOTIFICATIONS**

European Commission

SHARE    

23.08.2019

***The medical Devices section on the [website](#) of the Directorate General for Internal Market, Industry, Entrepreneurship and SMEs has been updated with new information related to the Medical Devices Regulation and / or the in vitro Diagnostic Medical Devices Regulation.***

***To see what's new, click on the following links:***

- [UDI system frequently asked questions and answers](#)

Internal Market, Industry, Entrepreneurship and SMEs

SHARE    

[Legal Notice](#) | [Unsubscribe](#) | [Preference Centre](#)

Funded under the Third Health Programme



# Accomplishments

- Mapping of relevant stakeholders (over 2000 contacts in and outside the EU) and outreach towards them via direct emailing, newsletters, social media targeting and phone follow up
- Online information hub created on DG GROW's website
- 5 Factsheets finalised – available on the website and disseminated to stakeholders
- 2 Step-by-step guides – available on the website and disseminated to stakeholders
- Pop-up /roll up/banner designs produced in multiple languages for stakeholders to use for their events and further dissemination
- Mapping of specialised media (approx. 1500 contacts in and outside the EU) and initial outreach (press release)

# Outputs > results

## Website Updates

- New section “New regulations” had peaks of activities in October, November and January resulting into 41 359 material downloads overall

## Contact programme stakeholders

- Reached over 1200 stakeholders (via email and newsletter)
- Engaged in over 600 phone follow-ups to make sure they are aware of the new regulation

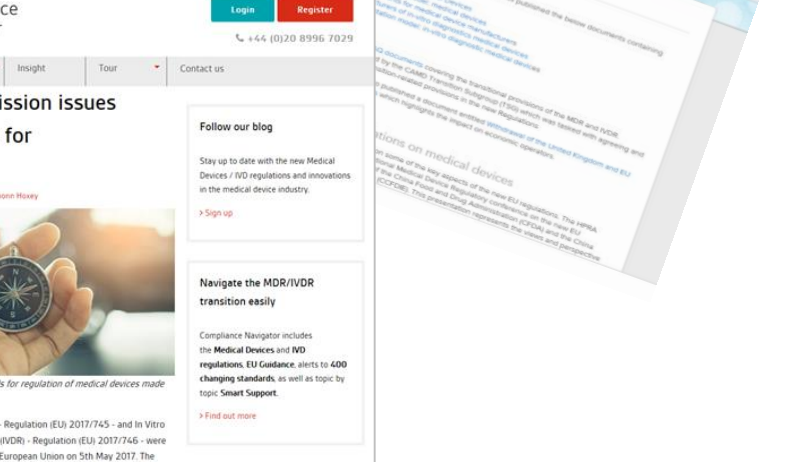
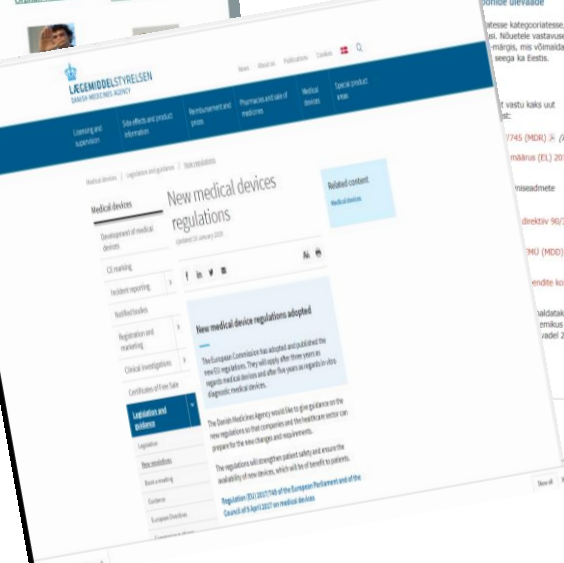
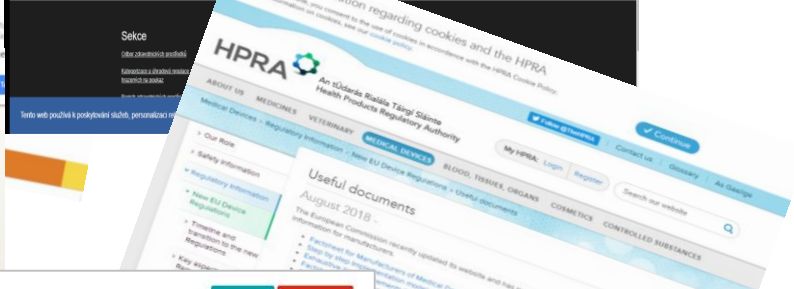
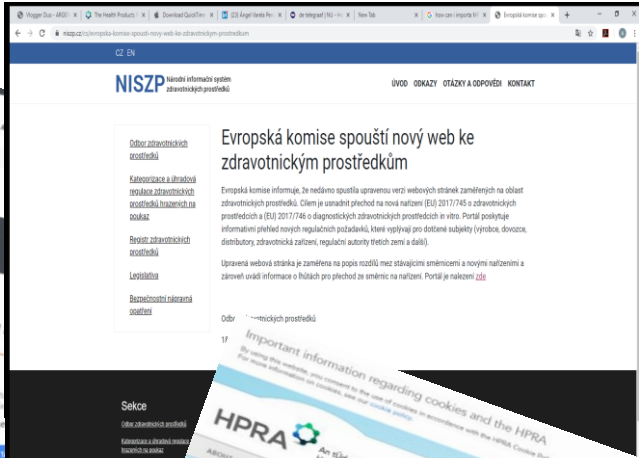
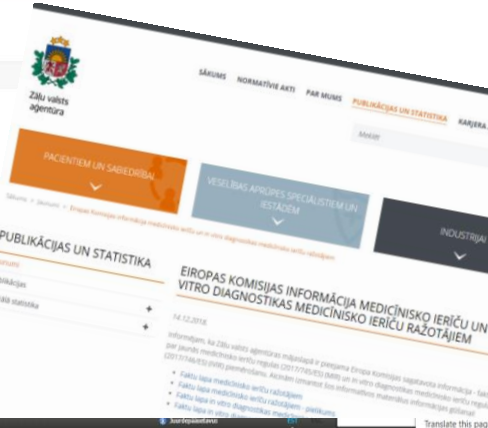
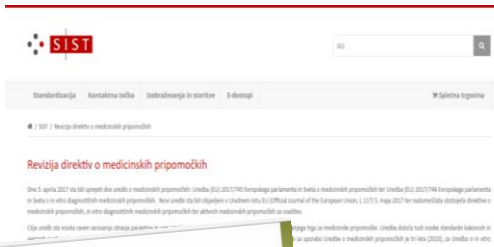
## Social media campaign on Twitter and LinkedIn

- Over 6000 link clicks (to the MD website)
- Almost 2 million impressions
- Almost 800 000 video views

## Media Relations

- Approximately 1500 specialised journalists mapped in the EU and outside
- Approximately 200 contacted by phone and other were reached out via press release

# Examples of National Competent Authorities' re-dissemination



# Examples of other stakeholders' re-dissemination

News

Revamped DG GROW website for medical devices

Posted on 10.01.2019

DG GROW launched a restructured website for medical devices which now has a **dedicated section** on the new in vitro Diagnostic Medical Device Regulation (EU) 2017/746 (IVDR) and Medical Device Regulation (EU) 2017/745 (MDR) and a **backlist** for various actors. The European Commission supports the transitioning with a series of factbooks, guides and infographics as part of its **tools**. The already published MDCG guidance documents may be found on **their dedicated page**.

VDE Medical Software

Blog Q/A Glossary Community Partners

EU MDR Factsheet for Manufacturers of Medical Devices

2019/01/03 - Guidance - 5 Questions - 5 Answers - by Cord Schlotterberg

Search

Username Password Remember Me Register Forgot Password Login

Top Experts

Thurstan Price 4 answers

Hans Christian Weiser 2 answers

CEpartner4U

Factsheet for Manufacturers of Medical Devices.

10 August 2018

Version	
Download	5
Stock	--
Total Files	1
Size	165.40 KB
Create Date	10 August 2018
Last Updated	11 September 2018

MDR\_2017/745/18

Source: <http://ec.europa.eu/growth/sectors/medical-devices/>

MEDCERT

Since 1994: On the course to success

Certification CE Marking ISO 13485 International Newsletter

EU: Guide for the implementation of the MDR and factsheet for manufacturers

CONTACT +49 40 226325 0

Sailab MedTech Finland

Tietopaketti MD- ja IVD-asetuksista

TUOTOJA VUOKAAN TAVARASTIIN

Yhteistyökumppani

Yhteistyökumppani

Yhteistyökumppani

ALLEN & OVERY Life Sciences Hub

Legal and regulatory developments in the Life Sciences sector

Getting ready for the EU MDR: New guidance documents available for manufacturers

21 August 2018 - Authored by Evelyne Van Keymeulen & Jacqueline Dore

During the summer months of July and August, the European Commission has published five documents aimed at guiding manufacturers and other economic operators through the changes implemented by the EU Medical Device Regulation (MDR) and the EU In Vitro Diagnostic Medical Device Regulation (IVDR). Both regimes will be fully applicable on 26 May 2020 and on 26 May 2022 respectively.

Search The Cove

New guidance sheets for the MDR/IVDR published

21.08.2018

New guidance sheets for the MDR/IVDR published

Transition Timelines from the Directives to the Regulations - Medical Devices and In Vitro Diagnostic Medical Devices

Implementation Model for Medical Devices Regulation - Step by Step Guide

Implementation Model for In Vitro Diagnostic Medical Devices Regulation - Step by Step Guide

Factsheet for Manufacturers of Medical Devices

Factsheet for Authorities in non-EU/EEA States on Medical Devices and In Vitro Diagnostic Medical Devices

BioSlice Blog

New guidance on the European Medical Devices and In Vitro Diagnostic Medical Devices Regulations

Home > New Guidance On The European Medical Devices And In Vitro Diagnostic Medical Devices Regulations

Hogan Lovells FOCUS ON REGULATION

European Commission publishes factsheet on medical devices and in vitro medical devices for non-EU and non-EEA competent authorities

POSTED ON JANUARY 17TH, 2019 BY ELISABETHANN WRIGHT AND ALEXANDER WENZEL

The European Commission has published a factsheet addressed to competent authorities of third countries. This factsheet is one of several guidance documents published by the European Commission to clarify points and answer questions regarding the implications of the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Device Regulation (IVDR).

Medical Device Regulation - MDR 2017/745 Consulting Service

Medical Device Regulation - MDR 2017/745 Consulting Service

With our team of SMEs and Regulatory experts we provide support to companies in different fields and with different kind of products going through the changes introduced by the new MDR.

Do you have any doubts about the new MDR? Reach out to us and we will help you clarify your situation

Name (required)

Email (required)

Message (required)

HPRRA Health Products Regulatory Authority

Medical Devices - Regulatory Information - New EU Device Regulations - Useful documents

Useful documents

August 2018 - The European Commission recently updated its website and has published the below documents containing information for manufacturers:

- Factsheet for Manufacturers of Medical Devices
- Step by step implementation model: medical devices
- Revised list of requirements for medical device manufacturers
- Factsheet for manufacturers of in-vitro diagnostic medical devices
- Step by step implementation model: In-vitro diagnostic medical devices

February 2018 - The CAMD network publishes FAQ documents covering the transitional provisions of the MDR and IVDR. These documents were developed by the CAMD Transition Subgroup (TSB) which was tasked with agreeing and providing greater clarity on the transition-related provisions in the new Regulations.

LEGEMIDDELSTYRELSEN DANISH MEDICINES AGENCY

Medical devices

Development of medical devices

Classification of products

CE marking

Notified bodies

Incident reporting

Registration and marketing

Clinical investigations

Certificates of Free Sale

Secure online shopping

Legislation and guidance

Location

New medical device regulations

updated 18 January 2019

Related content

Medical devices

The Danish Medicines Agency would like to give guidance on the new regulations so that companies and the healthcare sector can prepare for the new changes and requirements. The regulations will strengthen patient safety and ensure the



# The way ahead – 2<sup>nd</sup> phase of the campaign

## Objective

Raise awareness among stakeholders on the new Regulations and their requirements to avoid disruption of MD and IVD markets + patients' perspective later in the campaign

## Target groups

1. Manufacturers of MD and IVD in general
2. SMEs (umbrella organisations)
3. Competent Authorities
4. Notified bodies
5. Patient organisations

# The plan

## Tools/material foreseen

- ▶ Stakeholder mappings updated and new stakeholders mapped (SMEs and Patient Organisations)
- ▶ New information material/packs
- ▶ Website (review and update)
- ▶ Webinars
- ▶ New animated GIFs/visuals for website and social media
- ▶ Updated infographics
- ▶ Testimonials
- ▶ Newsletters, web notifications
- ▶ Conference kit
- ▶ Media kit
- ▶ Engagement kit

## Dissemination activities

- ▶ Website population
- ▶ Social media
- ▶ Stakeholders engagement and activation
- ▶ Very targeted specialised media outreach
- ▶ Supporting and participating in specialised events
- ▶ Other (media buying, etc.)

## Monitoring

- ▶ KPIs and regular analysis & reporting
- ▶ Daily media monitoring and monthly reporting

# The plan- Stakeholders mappings update and new mappings

- Full stakeholders mapping updated
- SMEs among MD and IVD manufacturers (umbrella organisations) mapped
- Patients organisations mapping underway
- Additional mappings – medical faculties and relevant contacts



# The plan – new information materials

## New factsheets/supporting materials

### Produced:

- Factsheet on Healthcare Professionals and Health Institutions
- UDI system document

### In preparation:

- Factsheet on Annex XVI
- Factsheet on Implant Card
- Factsheet on Software Medical Devices
- Factsheet on Transparency

The collage features several documents from the European Commission:

- Factsheet for healthcare professionals and health institutions:** A blue document with icons for a microscope, lungs, a syringe, glasses, a pencil, and a person. It includes the text: "This factsheet is aimed at healthcare professionals and health institutions. For a general overview of the impact of the Regulations please refer to the Medical Devices section on the website of the Directorate General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)." and "The new Medical Devices Regulation (2017/745/EU) (MDR) and the new In Vitro Diagnostic Medical Devices Regulation (2017/746/EU) (IVDR), adopted in May 2017, will replace the existing Medical Devices Directive (93/42/EEC) (MDD), the Active Implantable Medical Devices Directive (90/385/EEC) (AIMDD) and the In Vitro Diagnostic Medical Devices Directive (98/79/EC) (IVDD)."
- Introduction to the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR):** A document with a blue header and a photo of a medical scanner. It states: "The new Regulations will create a robust, transparent and sustainable regulatory framework, recognised internationally, that improves clinical safety and creates fair market access conditions for manufacturers." and "In contrast to directives, regulations are directly applicable and do not need to be transposed into national law. The MDR and the IVDR will therefore reduce the risk of discrepancies in interpretation across the EU."
- Unique Device Identification (UDI) System under the EU Medical Device Regulations 2017/745 and 2017/746:** A green document with icons for a person, a bicycle, a person with a cane, and a person with a wheelchair. It includes the text: "MEDICAL DEVICES CHANGE OF LEGISLATION What you need to know!" and "The new system will be applied to all medical devices except custom-made and performance study/investigational devices and is substantially based on internationally recognised principles, notably by using definitions that are compatible with those used by major trade partners."
- Introduction to the new system and the obligations of operators:** A document with a pink header and a photo of a hand holding a vial. It includes the text: "The new Regulations (Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices) entered into force on 26 May 2020 for medical devices and 26 May 2022 for in vitro diagnostic medical devices. The new Regulations will introduce an EU identification system based on a Unique Device Identifier (UDI)."

# The plan – website update /activity

## Online communication HUB on MDs and IVDs Regulations

- Search engine optimisation
- Updated information
- User-friendly structure of the website
- New section on patients as of next year

- ✓ Total document download until November 2019 is 103.277
- ✓ Latest website notification on UDI was opened over 5.000 times
- ✓ Total number of website visits (new pages) until November is 268.910

What is your area of activity?

The screenshot shows a navigation menu with the following categories:

- Manufacturers
  - Manufacturers IVD
  - Manufacturers MD
- Authorised Representatives, Importers and Distributors
- Competent authorities in non-EU/EEA countries
- Health institutions reprocessing single-use medical devices
- Healthcare professionals and health institutions
- Manufacturers of devices without an intended medical purpose
- The procurement of MDs and IVDs

A 'Share' button is located at the bottom right of the menu.

### Medical Devices

#### New Regulations

##### Getting ready

- Manufacturers MD
- Manufacturers IVD
- Competent authorities in non-EU/EEA countries
- Authorised Representatives, Importers and Distributors
- The procurement of MDs and IVDs
- Healthcare professionals and health institutions
- Health institutions reprocessing single-use medical devices
- Manufacturers of devices without an intended medical purpose

EUDAMED

Topics of interest

Dialogue with interested parties

## Webinars planned

- Webinar on Clinical Investigation, in collaboration with the European Society of Cardiology (ESC)
- Webinar on patients' rights, in collaboration with the European Patients' Forum (EPF)

\*with subtitles in different languages

# The plan – newsletters, web notifications, call for experts

MEDICAL DEVICES  
IN VITRO DIAGNOSTIC MEDICAL DEVICES  
GET READY FOR THE NEW REGULATIONS



What you need to know!

18.10.2019

## Newsletter

### MDR/IVDR – what's new?

As preparations continue for the application of the new Medical Devices Regulation (MDR) and In-Vitro Diagnostic Medical Devices Regulation (IVDR), now is a good time to update you on the latest news and recent developments.

Call for expression of interest  
Expert panels on medical devices and  
in vitro diagnostic devices



27 September – 10 November 2019



Call for experts on medical devices and in vitro diagnostic medical devices

**1 Sent to over 6000 subscribers**

MEDICAL DEVICES  
IN VITRO DIAGNOSTIC MEDICAL DEVICES  
GET READY FOR THE NEW REGULATIONS



WEB NOTIFICATIONS



SHARE    

11.07.2019

**The medical Devices section on the [website of the Directorate General for Internal Market, Industry, Entrepreneurship and SMEs](#) has been updated with new information related to the *Medical Devices Regulation* and / or the *in vitro Diagnostic Medical Devices Regulation*.**

**To see what's new, click on the following links:**

- [Call for clinical and other experts to be published later in 2019](#)

Internal Market, Industry, Entrepreneurship and SMEs

**5 Sent to over 2500 subscribers**

Call for expression of interest  
Expert panels on medical devices and  
in vitro diagnostic devices



27 September – 24 November 2019



**SUBMISSION DEADLINE  
EXTENDED!**

07.11.2019

**Notification on the 'Call for Experts on Medical Devices and In-vitro Diagnostic Medical Devices' - EXTENDED**

Dear Sir/Madam,

The European Commission has extended the call for expression of interest for expert panels on medical devices and *in vitro* diagnostic medical devices.

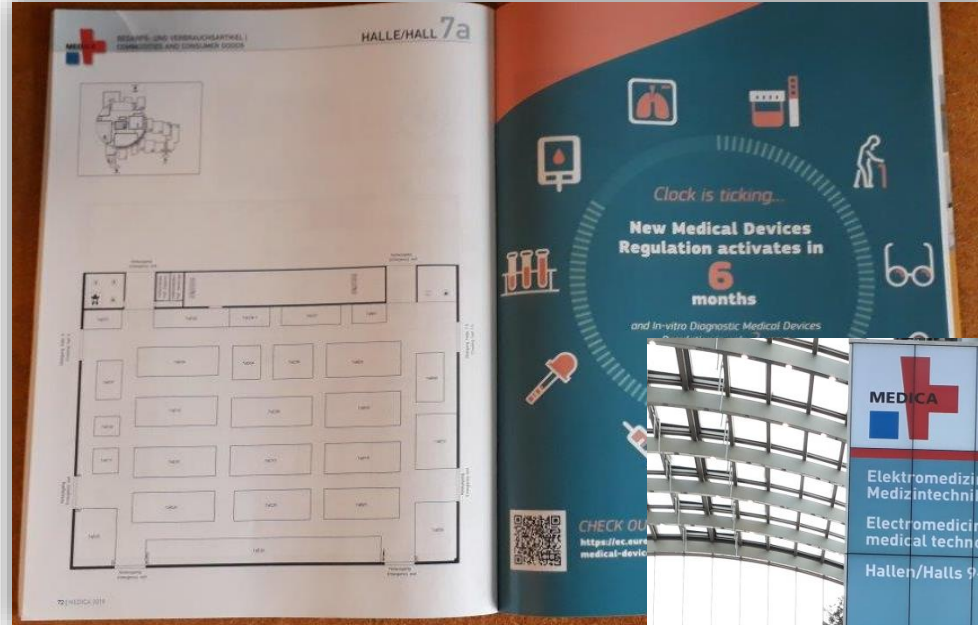
Interested candidates are invited to submit their application before **24 November 2019** through the following website:

[https://ec.europa.eu/growth/content/call-expression-interest-expert-panels-medical-devices-and-vitro-diagnostic-medical-devices\\_en](https://ec.europa.eu/growth/content/call-expression-interest-expert-panels-medical-devices-and-vitro-diagnostic-medical-devices_en)

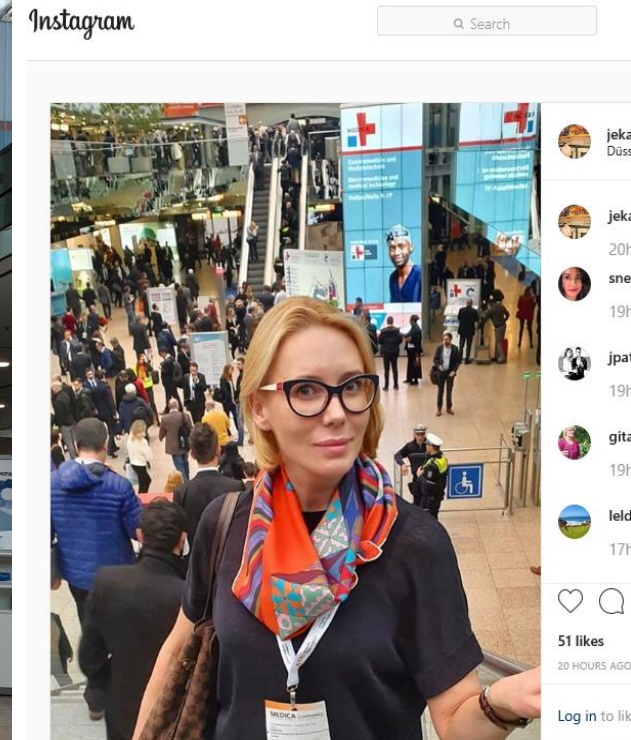
We would be grateful if you could distribute this call information and the

**2 Sent to over 9500 subscribers**

# The plan – conference kit/promotional material



- ## MEDICA Germany:
- Over 5 000 exhibitors
  - Over 100 000 visitors



## The plan

# Collaboration with JAMS

- Your feedback/suggestions?
- What are your communication needs?





# THANK YOU!

Contact: [aleksandra.lugovic@gopacom.eu](mailto:aleksandra.lugovic@gopacom.eu)  
[https://ec.europa.eu/growth/sectors/medical-devices/new-regulations\\_en](https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en)