Cambios en la MDR
Impacto en la industria:

La perspectiva de un organismo notificado

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VALENCIA

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Lo que vamos a ver

- El cambio
- El organismo notificado
- La Industria
- El Futuro

Antecedentes

El camino hacia las nuevas regulaciones de dispositivos médicos de la UE

- Las cuestiones de seguridad de los pacientes fueron el principal impulsor
  - PIPs
  - MoM
  - Malla del suelo pélvico
- Avances tecnológicos
  - Nanomateriales
  - Impresión 3D (dispositivos a medida)
- Cambios demográficos
  - Los dispositivos implantables a largo plazo se implantan durante más tiempo.
  - Los pacientes tienen mayor acceso a la información y se vuelven más exigentes y muestran mayores exigencias.

Requisitos generales de seguridad y rendimiento - Anexo I

- Hay 23 GSPRs en el MDR - 13 (Requisitos Esenciales) en el MDD

- 3 secciones -
  - Capítulo 1: Requisitos generales
  - Capítulo 2: Requisitos relativos al diseño y la fabricación
  - Capítulo 3: Requisitos relativos a la información suministrada con el dispositivo

Requisitos generales de seguridad y rendimiento - Anexo I

- Los GSPRs actúan como una guía de "cómo" cuando se desarrolla un Dispositivo o hacer un cambio significativo
- Son las normas que un organismo notificado exigirá a un fabricante cuando revise la documentación técnica.

- Ejemplo: GSPR 5:
  - Al eliminar o reducir los riesgos relacionados con los errores de uso, el fabricante deberá:
    - reducir en la medida de lo posible los riesgos relacionados con las características ergonómicas del producto y el entorno en el que está destinado a ser utilizado (diseño para la seguridad del paciente),

Documentación Técnica - Anexos II y III

- Existen dos anexos para la documentación técnica: uno sobre la documentación técnica general y otro sobre la vigilancia posterior a la comercialización.
- Al igual que en el caso de la GSPR, es necesario familiarizarse desde el principio
- El Anexo II está dividido en 6 secciones - coincide con el diseño del STED como se discutió anteriormente.
- Utilice los encabezados para generar un esqueleto de archivo técnico tan pronto como sea posible o pueda.

Documentación Técnica - Anexos II y III

- Descripción y especificación del dispositivo, incluyendo variantes y accesorios
- Información que debe facilitar el fabricante
- Información de diseño y fabricación
- Requisitos generales de seguridad y rendimiento
- Análisis de riesgos de beneficios y gestión de riesgos
- Verificación y validación del producto

Documentación Técnica - Anexos II y III

- El Anexo II es muy prescriptivo en cuanto a lo que se requiere en cada sección.
- Al igual que en el caso de los GSPR, el organismo notificado espera que se aborde cada uno de los elementos.
- Si está disponible, utilice los documentos de solicitud de los organismos notificados para complementar el desarrollo de un expediente técnico.

Documentación Técnica - Anexos II y III

- Anexo II, sección 3:

3. DESIGN AND MANUFACTURING INFORMATION

(a) information to allow the design stages applied to the device to be understood;

(b) complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation;

(c) identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.

- Documento de solicitud de KIWA:

Section 12: DEVICE TESTING

12.1 – Device Design Testing

1.	Please supply a Design Traceability Matrix or Design Input/ Output document and verify that the following have been included: • Design Input / User Need • Specification for each Input • Source of each specification • Justification of the source (via use of a standard: Harmonised, Non-Harmonised ASTM, AAMI), predicate device testing, internally validated specification with clinical feedback, etc.) • Design Output/ Documented Evidence • Comment on whether D/I was met or not

Documentación Técnica - Anexos II y III

- Anexo III - Documentación técnica sobre la vigilancia posterior a la comercialización
- Incluso para los nuevos dispositivos, un organismo notificado debe revisar el plan del (SPC) PMS.
- Capítulo VII - *Artículo 83* Sistema de vigilancia postventa
  - El fabricante debe planificar, implementar y actualizar un sistema PMS
  - Los datos que genera deben ser utilizados para:
    - Actualizar la determinación de riesgos de beneficios y mejorar la gestión de riesgos
    - Actualizar la evaluación clínica
    - Identificar la necesidad de medidas preventivas, correctivas o acciones correctivas de seguridad en todo el alcance.
    - Identificar la opción para mejorar la usabilidad, el rendimiento y la seguridad del dispositivo

Informe periódico de actualización de seguridad - Capitulo VII

- Artículo 86 - PSUR requerido para todos los dispositivos de las clases IIa, IIb y III
- Este es un resultado del plan de vigilancia post-comercialización que se detalla en el anexo III
- El PSUR debe:
  - Sacar conclusiones de la determinación del riesgo de beneficios
  - Esquema de las principales conclusiones de la PMCF
  - Indique el volumen de ventas, el tamaño de la población que utiliza el dispositivo y, si es posible, la frecuencia de uso.
- Intervalo:
  - Clases IIb y III: Al menos una vez al año.
  - Clase IIa: Cuando sea necesario y al menos cada dos años
- Clase III y dispositivos implantables deben tener PSUR aprobado por (NB) ON (Organismo Notificado)

Evaluación clínica y PMCF - Anexo XIV

- Evaluación clínica ≠ investigación clínica
- Todos los dispositivos requieren una evaluación clínica, independientemente de su clase.
  - El nivel de datos requerido dependerá de la clase
- MEDDEV 2.7/1 Rev.4 documento es una guía muy útil

Evaluación clínica y PMCF - Anexo XIV

- Anexo XIV - Parte A: Requisitos para un PAC
  - Identificar los datos clínicos disponibles relevantes para el producto y su finalidad prevista, así como cualquier laguna en la evidencia clínica a través de una revisión sistemática de la literatura científica.
  - Valorar todos los datos clínicos relevantes evaluando su idoneidad para establecer la seguridad y el rendimiento del dispositivo.
  - Generar, a través de investigaciones clínicas adecuadamente diseñadas de acuerdo con el plan de desarrollo clínico, cualquier dato clínico nuevo o adicional necesario para abordar los problemas pendientes.
  - Analizar todos los datos clínicos relevantes para llegar a conclusiones sobre la seguridad y el rendimiento clínico del dispositivo, incluidos sus beneficios clínicos.

Evaluación clínica y PMCF - Anexo XIV

- El Anexo XIV - Parte B establece los requisitos para la PMCF.
- Proceso continuo que actualiza la evaluación clínica
  - Para la clase III y los productos implantables deben actualizarse al menos una vez al año.
- Enlaces de vuelta con el anexo III - TD en PMS
- Su propósito es:
  - Confirmar la seguridad y el rendimiento del dispositivo a lo largo de su vida útil prevista
  - Identificar efectos secundarios desconocidos hasta ahora
  - Identificar y analizar los riesgos emergentes sobre la base de hechos.
  - evidencia
  - Garantizar la continua aceptabilidad de la relación beneficio-riesgo
  - Identificar el posible mal uso sistemático o uso fuera de la etiqueta

Evaluación clínica y PMCF - Anexo XIV

Evaluación clínica basada en la equivalencia

- Este proceso es más difícil en el marco de la MDR
  - **Técnico**: diseño similar; se utiliza en condiciones de uso similares
  - **Biológico**: el dispositivo utiliza los mismos materiales o sustancias en contacto con los mismos tejidos humanos.
  - **Clínica**: el producto se utiliza para la misma condición o propósito clínico, incluida una gravedad similar.
  - Debe ser equivalente a un único predicado para las tres categorías
- El elemento clave es que una diferencia no puede dar lugar a una diferencia clínicamente significativa en la seguridad o en el rendimiento clínico.
- El fabricante debe tener suficiente acceso a los datos de los productos equivalentes.

Evaluación clínica y PMCF - Anexo XIV

Evaluación clínica de dispositivos heredados

- MDR no tiene cláusula de derechos adquiridos
- Todos los dispositivos serán tratados como nuevos cuando sean revisados.
- ¿Qué calidad tienen actualmente sus datos clínicos?

Evaluación clínica y PMCF - Anexo XIV

Evaluación clínica de dispositivos heredados

- ¿Qué datos clínicos puede recopilar para incluirlos en la (CER)RCE?
  - Contabilizar datos de mercado:
    - PMCF
    - Encuesta sobre la experiencia del usuario
    - Registro
    - Datos de las reclamaciones
    - Informes de vigilancia
    - Grupo de usuarios expertos
  - Pruebas en banco
  - Revisión de la literatura científica

El organismo notificado

Números actuales de los organismos notificados

- Actualmente ~45 en todos los códigos
- No todos son iguales!
- Código NANDO MD0105: Dispositivos Oftalmológicos: 40 organismos notificados disponibles
- Algunos organismos notificados pueden figurar en la lista por separado, pero son una oficina regional de una oficina más grande.

El organismo notificado

Números de los futuros organismos notificados

- Predicción de que el número podría bajar a 35-40
- Puede que se consolide
- Podría ver a los organismos notificados "especializados" que están surgiendo

- Razón:
  - Requisitos de designación - competencia, interna vs. contrato
  - Pasivo financiero
- Impacto en la capacidad

El organismo notificado

Números actuales y situación de los futuros organismos notificados para el reglamento

- Actualmente hay 38 organismos que han solicitado la opción de MDR 745 y 8 de IVDR, están en distintas fases.
- Actualmente hay solo 7 organismos notificados para el MDR 745
- Hay 10 mas en estado de publicación para final 2019 ?.
- Existen 10 a la espera de auditoria , han pasado revisión documentación.
- Existen 10 mas en proceso de revisión de documentación y el resto hasta los 46 están recopilando la documentación para el envió del dosier.
- Estos datos son dinámicos !!!!

Notified Bodies (NBs) –
A Key Pillar of the Medical Technology Regulatory System

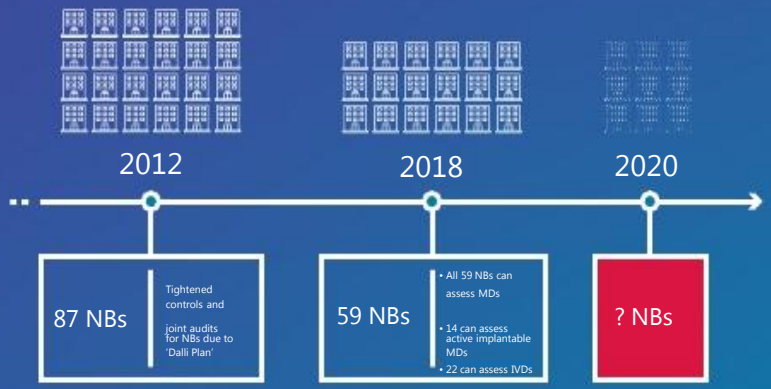
Notified Bodies are responsible for assessing medical devices (MDs) and in vitro diagnostics (IVDs). They are an indispensable part of the regulatory system since they grant a CE mark to each device before it can be placed in the EU market.

Notified Bodies are undergoing a significant revamp in order to comply with their greater obligations according to the new Medical Device and In Vitro Diagnostic Regulations.

Key facts about Notified Bodies

- Independent
- Impartial
- Designated and supervised by National Authorities
- Grant EU-wide product approval
- Public or private
- Identified by a 4-digit number, placed with the CE mark

How many Notified Bodies (re-)certify MDs and IVDs?*



Countries can have a different amount of NBs: none, one or several

*EC NANDO database

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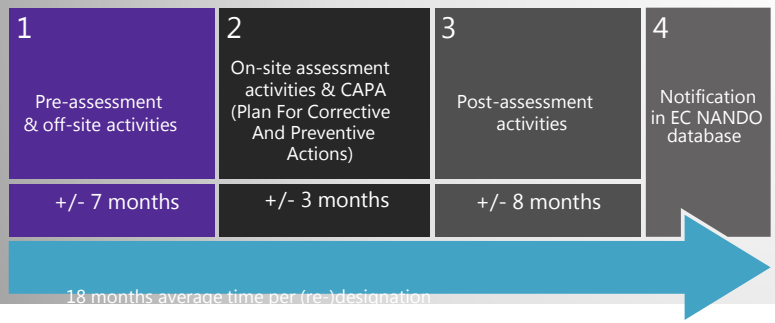
(Re-)Designation of All Notified Bodies (NBs) Under the New Regulations

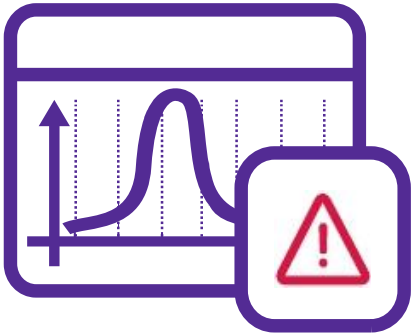
All existing and new Notified Bodies need to be designated to prove their competence in assessing products and quality systems under the increased requirements of the new regulations. This designation process includes four steps and is expected to take on average 18 months per Notified Body (source: NBOG).



The designation procedure started on 26 November 2017.

First Notified Bodies are expected to be designated in Q2/2019.

The Notified Body system will face a crunch time



- The new regulations came into force on 26 May 2017; the dates of application are 26 May 2020 for MDs and 26 May 2022 for IVDs.
- From the dates of application, only NBs that are designated for the new regulations can assess and (re-)certify products.
- Before that date, 314.000 of 500.000 MDs and 35.000 of 40.000 IVDs currently CE marked need to be (re-)certified to remain on the EU market.
- The 'grace period' does not solve the excessive work load that NBs face before May 2020 because:
  – many products are not eligible for the 'grace period';
  – eligible products would still need to be re-certified by May 2020.

What is the 'grace period'? It allows for certain devices to be placed on the market with a valid certificate based on the IVD/AIMD/MD Directives. This period starts from the date of application of the new Regulations to until 26 May 2024.

A Massive Increase in Notified Body (NB) Workload

Today

With 30% fewer NBs and tighter controls than in 2012, many NBs are already overstretched with (re-)certifications under the current IVD/AIMD/MD Directives, triggering delays in approval of products.

Tomorrow

NBs will have to follow additional and more stringent requirements under the new regulations (e.g. on clinical and post-market surveillance aspects). This will have further impact on the available time to review products.

Three main challenges

Lack of time

NBs have insufficient time between their designation and the dates of application of the new regulations to perform the required (re-)certification of products including:

- All CE marked products that are already on the market (re-certification);
- Products that will have Notified Bodies oversight for the first time (certification):
  - 85% of all IVDs;
  - Certain MD categories such as reusable surgical instruments;
- New and innovative products certification.

Lack of capacity

NBs need more capacity to absorb higher amounts of work. The current capacity challenge is further expanded because:

- None of the 59 existing NBs has yet been designated (as of July 2018);
- It is expected that not all 59 NBs will apply and succeed with the designation;
- Brexit risks to decrease the certification capacity by 30-40% that is currently carried out by UK Notified Bodies;
- NBs must continue to certify products while being (re-)designated to the new regulations.

Lack of available experts

NBs are facing challenges in finding, hiring and training staff to address the requirements of the new regulations:

- Additional expertise to check products against the new requirements is not sufficiently available;
- In-house staff has one to two years learning curve to be fully operational.

Too few appropriately staffed Notified Bodies will be available early enough to absorb the workload prior to the dates of application of the new regulations.

Foreseen Consequences

For manufacturers

- Impossibility today to file products for certification under the regulations until Notified Bodies are available;
- Lack of business predictability due to lack of clarity about which NB will have capacity at what point in time and for which product categories;
- Increased waiting time to obtain CE marking;
- Increased vulnerability and uncertainty for SMEs, which represent 95% of the sector;
- Disruption in the supply chain.

For patients, healthcare professionals, hospitals and laboratories

High risk of delay or discontinuation of access to medical technology products.

For the EU as a whole

Potential loss of competitiveness against other global constituencies (US, China, etc).

Previsión de los diferentes plazos para aplicación del Reglamento.

- Situación Previsión a Mayo 2019
- Hay cambios continuos en los plazos .
- Estar atentos a los nuevos documentos que se publicaran desde la CE.
- Hay un Draft con las especificaciones del Anexo XVI sobre los productos de Estética.
- Retrasos en la base de datos EUDAMED hasta 2021 etc.

Implementation Timeline : What is done ?

✓ **Q3 2017**

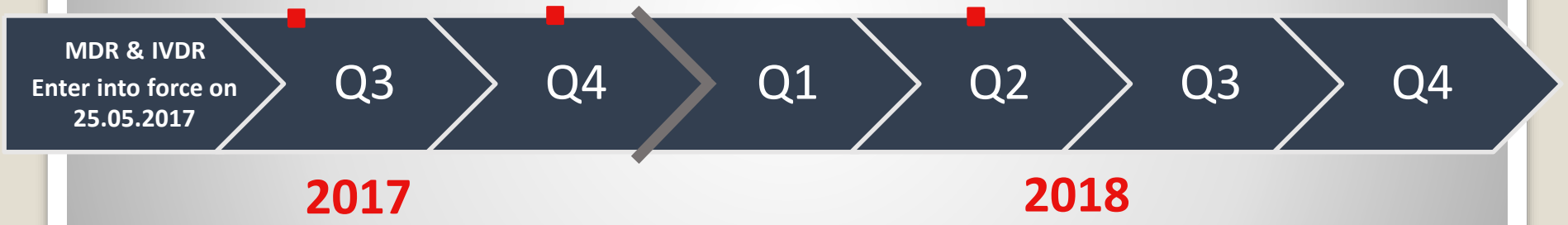
Mandate SCHEER committee to prepare guidelines of phthalates : Hyperlink
SCHEER's opinions expected by mid 2019: Annex 1 section 10.4.3 MDR

✓ **Q4 2017**

« NB scope of designation »
Article 42 (13) MDR, Article 38 (13) IVDR
ImplementingRegulation (EU) 2017/2185
NBOG MDR FORM
NBOG IVDR FORM
Expert advisory structure: Setting of MDCG
Article 103 MDR - Minutes

✓ **Q2 2018**

EUDAMED « Implementation plan » Article 34 (1) MDR



✓ **Done during 2018**

« ~~Communication Campaign~~ »
- Factsheet for IVD and MD manufacturers
- Implementation modele for MDR
- Transition Timelines from the Directives to the Regulations - MDs and IVDs
- Factsheet for Authorised Representatives, Importers and Distributors of MDs and IVDs
- Factsheet for Authorities in non-EU/EEA States on MDs and IVDs
- Factsheet for the Procurement Ecosystem of MDs and IVDs

EU Regulations 2017/745 & 746// What's coming next ?

✓ **Q1 2019**

- **Expert advisory structure: Setting of MDCG subgroups** Article 103 MDR - 10 Subgroups List
- **« EU MD's nomenclature » :** Article 26 MDR, Article 23 IVDR Guidance MDCG – MD nomenclature
- **EUDAMED « drawing up of functional specifications »** Article 34 (1) MDR - EUDAMED functionalspecifications

▪ **Q2 2019**

- **« Standardization mandate » :** Article 10 R (EU) No 1025/2012
- **« UDI System : designation of issuing entities »** Recital 94 – Article 27 (2) MDR, Recital 94 – Article 24 (2) IVDR
- **Implementing act – Common specifications related to reprocessing of single-use MD – Public consultation** Article 17 (5) MDR

▪ **Q3 2019**

« Setting up of experts panels » : No Comitology Involved - Recital 94 Article 106 (1) MDR

Q1 Q2 Q3 Q4

2019

▪ **Q4 2019**

- **« Reprocessing of single use MD » :** Article 17 (5) MDR ❼National sovereignty
- **« Definition of fees for the advice provided by expert panel » :** Article 106 (13) MDR
- **EUDAMED Change management and maintenance rules :** Article 33 (8) MDR , Article 30 (1) IVDR
- **« Common specifications for IVD Class D » :** Articles 9 and 48 (6) IVDR

▪ **Q4 2019 (until Q1 2020)**

- **« Rules to facilitate fulfilment of tasks by EURL and to ensure their compliance with criteria » :** Article 100. 8 (a) IVDR
- **« Setting up of new structuresunder IVDR : EURL » : No Comitology Involved -** Recital 94 – Articles 48 (6) and 100 (1) IVDR

2020 : A regulatory Odyssey

+ 2 YEARS BEFORE IVDR LEGAL DEADLINE 26/05/2022

- **Q1 2020**
  - **« EUDAMED : Setting of helpdesk »** Article 33 (8) MDR **:** to be done just before **-> « EUDAMED : go-live » (as soon as a notice is published in the OJEU) :** Article 34 MDR
  - **EUDAMED « Audit of functional specifications » :** Article 34 (2) MDR
  - **« Common specifications for products without a medical purpose » :** Articles 1 (2) and 9 (1) MDR

26/05/2020 - LEGAL DEADLINE
(EU) 2017/745 MDR become mandatory

2020

- **Q2 2020**
  - **« Definition of fees for the advice/testing activities performed by EURL » :** Article 100 (8) b MDR
  - **« Notified bodies designation » to be finished by may 2020 :** Article 42 MDR
  - **« Setting up of experts laboratories » : No Comitology Involved :** Article 106 (7) MDR

La Industria

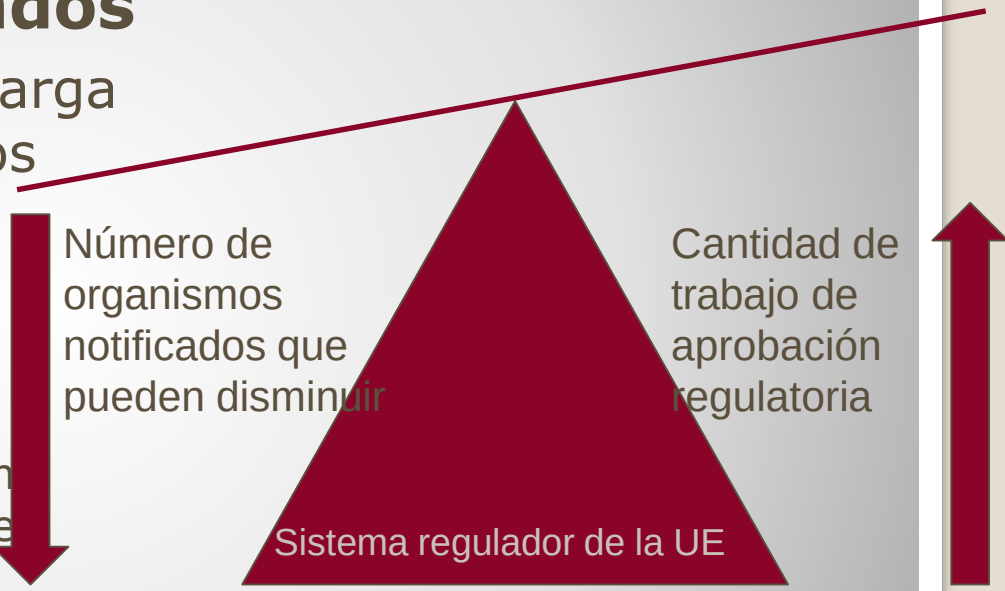
Problemas de recursos

- ¡Todo el mundo está contratando!
  - Comisión Europea
  - Autoridades competentes
  - Organismos notificados
  - Fabricantes
- Carga de trabajo real
  - Inicialmente, cumplir con nuevos requisitos/obtener la certificación por primera vez
  - Mantener el mayor nivel de trabajo regulatorio

La Industria

Acceso a los mercados

- Posiblemente una ruta más larga hacia el mercado para nuevos dispositivos
  - Requisitos de capital
- Registro del producto desorganización
  - Todos los dispositivos deben estar certificados inicialmente bajo MDR - factor tiempo
  - Marca CE aceptada en muchas jurisdicciones o paises terceros.
- Interrupción del suministro



La Industria

Ajuste de Oferta PS

- Retirada de productos
  - Costo de adaptación vs ingresos por producto
- Retirada temporal mientras se generan los datos
  - No planear a tiempo!
- Presión de precios
  - El costo de la adaptación al MDR puede hacer que su dispositivo quede fuera del mercado

La Industria

Datos clínicos - UE vs. EE.UU. - Regulatorio vs. Reembolso

- Percepción
  - Los requisitos reglamentarios de la UE se vuelven demasiado difíciles
  - EE.UU. es ahora un objetivo menos ambicioso para la entrada en el mercado
- Realidad
  - Los requisitos reglamentarios de la UE están aumentando, pero no de forma espectacular
  - Los requisitos de datos clínicos en la UE son cada vez mayores
  - Será necesario realizar un mayor número de ensayos clínicos
  - La FDA está tratando activamente de reducir los tiempos de aprobación
  - La aprobación de la FDA **no** equivale a la entrada total en el mercado de EE.UU.

La Industria

Datos clínicos - UE vs. EE.UU. - Regulatorio vs. Reembolso

- Reembolso en EE.UU.
  - El objetivo es demostrar que su dispositivo es "Razonable y Necesario".
  - Puede ser difícil probar lo anterior sin datos clínicos empíricos.

La Industria

Datos clínicos - UE vs. EE.UU. - Regulatorio vs. Reembolso

- Ideal World - ensayo clínico que permitirá
  - Entregar los datos de seguridad, eficacia y rendimiento necesarios para la aprobación reglamentaria (FDA y marca CE).
  - Demostrar que su dispositivo es "Razonable y Necesario" y puede aportar algún beneficio económico - facilitar la vía de reembolso
  - Entregar los puntos finales que se reclaman en su IFU
  - Presente un mensaje claro y comercial del rendimiento de sus dispositivos
- Necesitará datos clínicos en algún momento - hágalo una vez, hágalo bien.

El Futuro

Oportunidades creadas

- Necesidades satisfechas anteriormente se convierten en necesidades no satisfechas
  - Eliminación de productos existentes
- Una estrategia regulatoria proactiva puede dar ventaja en la carrera hacia el mercado
  - Adopción temprana de aspectos de MDR en el desarrollo de productos

El Futuro

Oportunidades creadas

- Nueva regulación que actúa como barrera a la entrada desde el "exterior" para compañias nuevas en el sector.
  - Industria tecnológica
  - ¿Quién mejor para navegar por los reglamentos de MD que la industria de MD?
- Mayor potencial de adquisición para dispositivos que cumplen con las normas de forma precoz
  - Grandes empresas que compran dispositivos similares para utilizarlos en mercados adecuados.

El Futuro

Fuentes de Nueva documentación MDR 745

New version of the European Commission' IVDR/MDR rolling plan

Posted on 28.02.2019

Implementation Rolling Plan was published on 19 February and provides updated timing and next steps for the development of implementing regulations and other actions/initiatives.

1) **MDR Annex XVI products without an intended medical purpose:** Q1 2019' is the new date for the Commission's informal consultation on the draft text of the common specifications. The December version indicated 'by beginning 2019'. Also target date is moved from November 2019 to Q1 2020.

2) '**Scientific bodies' (i.e., expert panels, EU reference laboratories and expert laboratories)**: For the various implementing acts the surveys are now marked as 'finalised' (as in December 2018). Only change: the move into drafting stage for the act on expert panels.

3) **Eudamed**: drawing up of functional specifications - EUDAMED for PMS and clinicals may be only partly available or not at all by the date of application.

4) **Communications campaign**: The new dedicated website and first updated library are live. New factsheets have been published in January 2019. Release of existing factsheets in some major non-EU languages has also started. Social media campaign under preparation.

5) **Medical Device Coordination Group (MDCG) subgroups**: the evaluation of the applications is still ongoing, and that the new MDCG subgroups are expected in Q1 2019.

6) **EU Medical devices nomenclature** – the Commission is currently finalising its assessment in the view of a final decision to be taken by Q1 2019.

7) **Notified Body designation**: 42 applications received by the EC, 3 further joint assessments scheduled (apart from the 25 already carried out).

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Fuentes de Nueva Documentación MDR 745

New guidance documents from the Medical Devices Coordination Group

Posted on 28.02.2019

The Medical Devices Coordination Group (MDCG) recently published a short guidance on the content of the certificates and voluntary certificate transfers, which can be found here. This short document explains the importance of providing traceability to common specifications and harmonised standards, even if they are not listed on the certificate itself. For voluntary certificate transfer from one notified body to another: while full conformity assessment procedures may not be needed if the incoming notified body receives sufficient information, the document outlines some minimum procedures which should be followed.

The MDCG also endorsed additional/updated guidance documents which support the Unique Device Identification implementation under the upcoming IVD and MD Regulations:

1. MDCG 2019-1 MDCG guiding principles for issuing entities rules on Basic UDI-DI (January 2019)
2. MDCG 2019-2 Guidance on application of UDI rules to device-part of products referred to in Article 1(8), 1(9) and 1(10) of Regulation 745/2017 (February 2019)
3. MDCG 2018-1 v2 Draft guidance on basic UDI-DI and changes to UDI-DI (February 2019)

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Fuentes de Nueva documentación MDR 745

Updated MDR/IVDR Implementation Rolling Plan

Posted on 30.01.2019

Last month, the European Commission published an updated version of its MDR/IVDR Implementation Rolling Plan – click here. This document provides timing and next steps for the development of implementing regulations and other actions/initiatives.

Please find below a list of changes compared to the original version, which was published in October:

•**MDR Annex XVI products without an intended medical purpose**: 'Beginning 2019' is the new date for the Commission's informal consultation on the draft text of the common specifications. The original version of the rolling plan gave 'Q3 2018' as the estimated timeline.

•**'Scientific bodies' (i.e., expert panels, EU reference laboratories and expert laboratories)**: For the various implementing acts covering these bodies, the original version of the rolling plan referred to an 'ongoing' survey of MDCG members and stakeholders. This survey is now marked as 'finalised.'

•**Communications campaign**: The original version of the rolling plan indicated that more factsheets were scheduled to be produced by Q4 2018. The new version captures that these additional factsheets were published in November 2018.

•**Medical Device Coordination Group (MDCG) subgroups**: The new version of the rolling plan indicates that the call for stakeholder applications expired on 15 November, and that the new MDCG subgroups are expected to be established in Q1 2019.

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Fuentes de Nueva documentación MDR 745

Status of designation of UDI issuing agencies in Europe

Posted on 30.01.2019

The deadline for the UDI issuing agencies to apply for designation in accordance with Article 27(2) of Regulation (EU) 2017/745 (MDR) and Article 24(2) of Regulation (EU) 2017/746 (IVDR) expired on Friday, 25 January 2019. After the assessment of the received applications, an Implementing Act on the designation of UDI issuing entity/ies will be published - according to DG GROW's implementation rolling plan latest by 26 May 2019. In the meantime, the MDCG approved guiding principles for issuing entities on Basic UDI-DI were also published.

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- **New Links Added in May 2019**
- Software as medical device (SaMD) Regulating software as a Medical Device in the Age of Artificial
- Intelligence (RAPS). https://www.raps.org/news-and-articles/news-articles/2019/5/regulating-software-
- as-a-medical-device-in-the-age
- **New updates on the MDR and IVDR**
- EMA First Guidance on new rules for certain medical devices (February 2019).
- https://www.ema.europa.eu/en/news/first-guidance-new-rules-certain-medical-devices
- EUDAMED UDI Device Data Dictionary: https://ec.europa.eu/docsroom/documents/35243?locale=e
- MDR-UDI https://ec.europa.eu/docsroom/documents/35241?locale=en
- IVDR-UDI https://ec.europa.eu/docsroom/documents/35242?locale=en
- MDR Corrigendum March 2019 https://data.consilium.europa.eu/doc/document/ST-15409-2018-REV-
- 1/en/pdf
- IVDR Corrigendum March 2019 https://data.consilium.europa.eu/doc/document/ST-15418-2018-REV-
- 1/en/pdf
- Best practices in MDR Documentation Submissions from BSI
- https://www.bsigroup.com/globalassets/meddev/localfiles/en-gb/documents/bsi-md-mdr-best-
- practice-documentation-submissions-en-gb.pdf
- **Combination products**
- An Assessment of Concerns Regarding New Regulatory Guidance (FDA) for Combination Products
- https://journals.sagepub.com/doi/abs/10.1177/2168479018775659?journalCode=dijc
- EMA First Guidance on new rules for certain medical devices (February 2019).
- https://www.ema.europa.eu/en/news/first-guidance-new-rules-certain-medical-devices
- **Brexit info**
- BSI Medical Devices and Brexit webpage. https://www.bsigroup.com/en-GB/medical-
- devices/brexit-medical-devices/
- Medical devices in the UK after Brexit.
- https://www.legislation.gov.uk/ukdsi/2019/9780111179260/pdfs/ukdsi_9780111179260_en.pdf
- **Other information**
- The International Medical Device Regulators Forum (IMDRF) releases final guide to submission
- documents in March 2019.http://www.imdrf.org/documents/documents.asp
-
- The European Medical Technology Industry 2018. https://www.medtecheurope.org/about-the-
- industry/facts-figures/
-

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European Commission

EC Medical Devices Unit https://ec.europa.eu/growth/sectors/medical-devices_en

New 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

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

Guidance documents to the new regulations

Title

European Competent Authorities for Medical Devices

https://www.camd-europe.eu/

MDR and IVDR Transitional FAQs https://www.camd-europe.eu/regulatory/available-now-mdr-ivdr-transitional-faqs/

Medical Devices Regulation/In-vitro Diagnostics Regulation (MDR/IVDR) Roadmap https://www.camd-europe.eu/regulatory/medical-devices-regulation-vitro-diagnostics-regulation-mdr-ivdr-roadmap/

Joint Action on Market Surveillance of Medical Devices (JAMS) https://www.camd-europe.eu/joint-action-projects/market-surveillance-of-medical-devices-jams/

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Notified Bodies

List of EU Notified Bodies

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

http://www.nbog.eu/nbog-documents/

Designation of notified bodies under the new Regulations on medical devices

Notified BODIES Designation of notified bodies under the new Regulations on medical devices

1. Best practice guidance on designation and notification of conformity assessment bodies (NBOG BPG 2017-1)
2. Best practice guidance on the information required for conformity assessment bodies' personnel involved in conformity assessment activities (NBOG BPG 2017-2)
3. Application form to be submitted by a conformity assessment body when applying for designation as notified body under the medical devices Regulation (MDR) (NBOG F 2017-1)
4. Application form to be submitted by a conformity assessment body when applying for designation as notified body under the in vitro diagnostic devices Regulation (IVDR) (NBOG F 2017-2)
5. Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/745 (MDR) (NBOG F 2017-3)
6. Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/746 (IVDR) (NBOG F 2017-4)
7. Preliminary assessment review template (MDR) (NBOG F 2017-5)
8. Preliminary assessment review template (IVDR) (NBOG F 2017-6)
9. Review of qualification for the authorisation of personnel (MDR) (NBOG F 2017-7)
10. Review of qualification for the authorisation of personnel (IVDR) (NBOG F 2017-8)

MHRA Guidance to Notified Bodies

https://www.gov.uk/government/publications/notified-bodies-for-medical-devices/notified-bodies-for-medical-devices

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- **Nomenclature and UDI**

- Publication of first UDI guidance and requirements for medical device nomenclature: March 2018
- https://ec.europa.eu/growth/sectors/medical-devices/guidance_en

Reference	Title	Publication date
MDCG 2018-1	Draft guidance on basic UDI-DI and changes to UDI-DI	March 2018
MDCG 2018-2	Future EU medical device nomenclature – Description of requirements	

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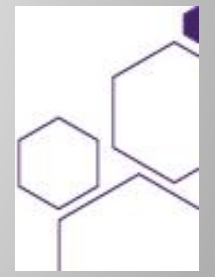
- **Safety**
- Adverse event reporting from clinical investigations https://ec.europa.eu/growth/sectors/medical-devices/guidance_en
- Mandate to SCHEER to produce guidelines On the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting properties
- https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_q_009.pdf
- **Other resources and news**
- Value and Use of Patient Reported Outcomes in in Assessing Effects of Medical Devices
- https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM588576.pdf
- Software als Medizinprodukt (German)
- http://www.xing-news.com/reader/news/articles/1472724?cce=em5e0cbb4d.%3Auyu72CakZNu7uDIDUTPbAP&link_position=digest&newsletter_id=34464&toolbar=true&xng_share_origin=email
- A New Era for Medical Devices: Current Regulatory Issues
- https://globalforum.diaglobal.org/issue/june-2018/a-new-era-for-medical-devices/?_ga=2.150857974.1720312607.1534013672-1287427849.1534013672
- Resource library for medical device professionals (EMERGO)
- https://www.emergobyul.com/resources
- BSI Medical devices Resources white papers series
- https://www.bsigroup.com/en-GB/medical-devices/resources/whitepapers/

Datos interesantes del mercado de productos sanitarios

>675,000 employees[3]

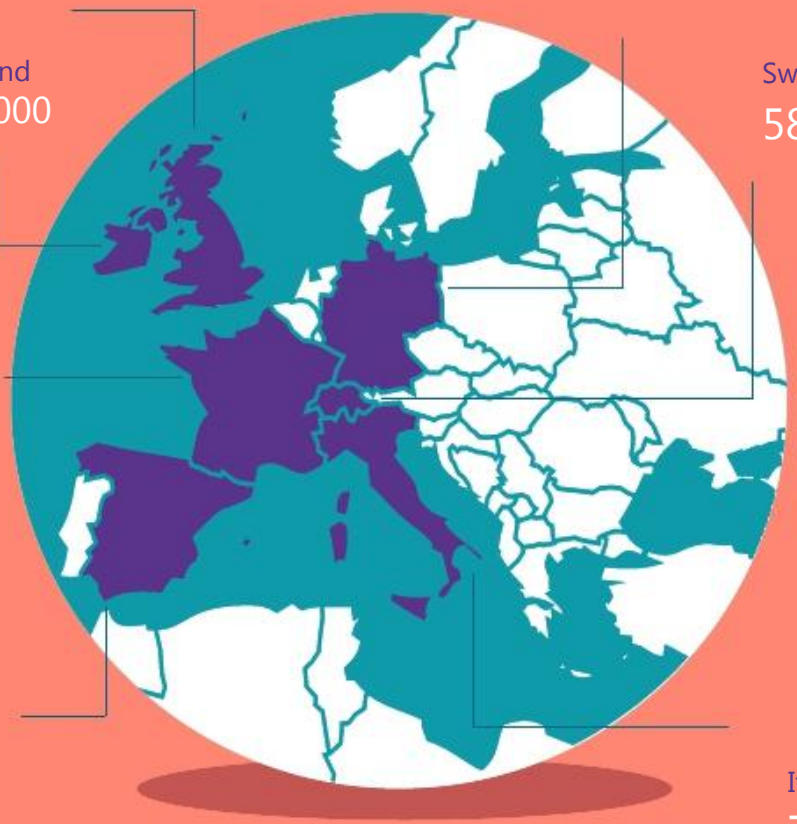
The European medical technology industry employs directly more than 675,000 people. Germany has the highest absolute number of people employed in the medical technology sector, while the number of medtech employees per capita is highest in Ireland and Switzerland. This high level of employment shows that the medical technology industry is an important player in the European economy.

In comparison, the European pharmaceutical industry employs more than 750,000 people[2].

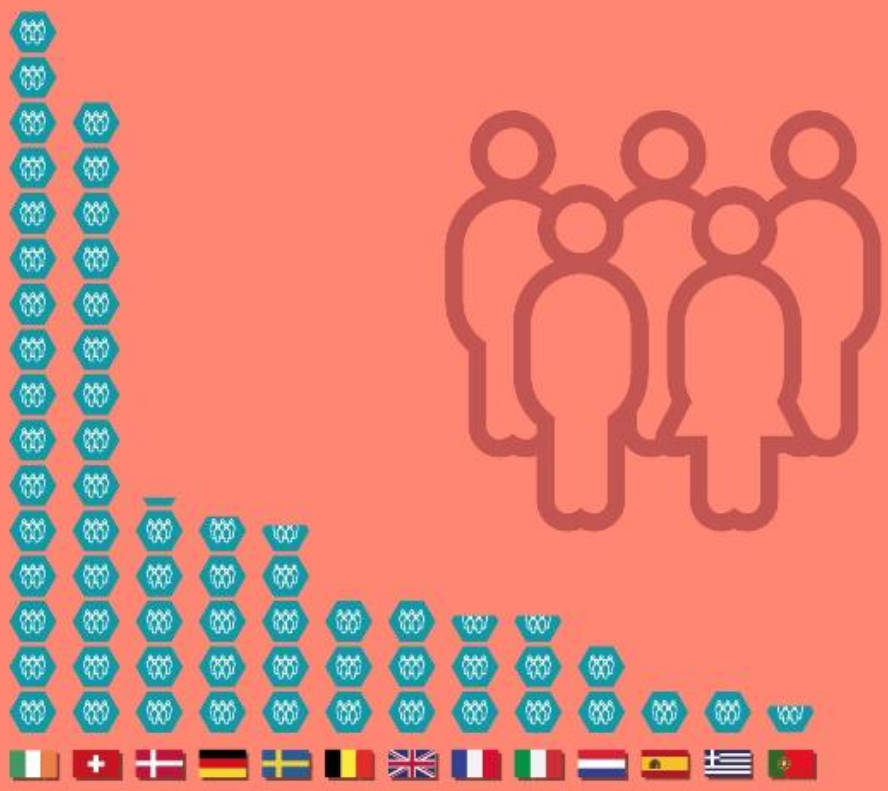


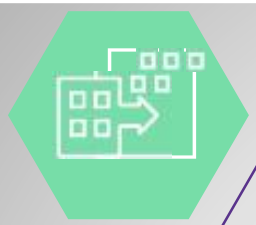
Europe refers to EU 28, Norway and Switzerland unless specified otherwise.

Top 7 countries with highest direct employment in the medical technology industry, 2017 (ref. 3)



Number of people directly employed in the medical technology industry per 10,000 inhabitants, 2017 (ref. 3)





27,000
medical technology companies in Europe

95%
SMEs

There are almost 27,000 medical technology companies in Europe.
Most of them are based in Germany, followed by the UK, Italy, Switzerland, Spain and France. Small and medium-sized companies (SMEs*) make up around 95% of the medical technology industry, the majority of which employ less than 50 people (small and micro-sized companies)[3].

**An enterprise is considered to be a SME if it employs fewer than 250 persons and has an annual turnover not exceeding €50 million (small company- employs fewer than 50 persons and has a turnover of less than €10 million).*

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Expenditure on medical technology per capita in Europe

In Europe, an average of approximately 10% of gross domestic product (GDP) is spent on healthcare. Out of the total healthcare expenditure, around 7.2% is attributed to medical technologies, i.e. less than 1% of GDP. The spending on medical technology is estimated to vary significantly across European countries, ranging from around 5% to 10% of the total healthcare expenditure[4]. Expenditure on medical technology per capita in Europe is at around €213 (weighted average).

10%

of GDP spent on healthcare

€115
billion market

The European medical technology market is estimated at roughly €115 billion in 2017.

Based upon manufacturer prices, the European medical technology market is estimated to make up 27% of the world market. It is the second largest medical technology market after the US (+/- 43%)[6].

27%
of the world market

2nd
largest market after US

European medical device market by country, based upon manufacturer prices, 2017 (ref. 6)

GRACIAS!

Las Preguntas son bienvenidas

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