Transition to the MDR/IVDR - Update

LSA – Lübeck Summer Academy on Medical Technology 2019
Lübeck, June 26th, 2019

Prof. Dr. Folker Spitzenberger, PhD, M.D.R.A.

Centre for Regulatory Affairs in Biomedical Sciences - CRABS

Technische Hochschule Lübeck University of Applied Sciences

TECHNISCHE HOCHSCHULE LÜBECK

May 2020 MDR Deadline is 'Realistic and Achievable,' EU Health Commissioner Says

Posted 14 June 2019 | By Zachary Brennan

While acknowledging that the May 2020 deadline for the implementation of the new medical devices regulation (MDR) is a "significant challenge," the European Commissioner for Health and Food Safety said Friday that the industry and government "are on course to meet it."

Vytenis Andriukaitis's comments at a meeting of EU Ministers for Employment, Social Policy, Health and Consumer Affairs (EPSCO) in Luxemburg followed concerns raised this week by German and Irish delegations to the Council of the EU over notified body (NB) capacity and the implementation of MDR.

As far the "crucial issue" of NBs, Andriukaitis said 51 NB applications have been received by the EC as of Thursday, 29 joint assessments have been performed and the two biggest NBs have been designated (BSI and TÜV SÜD) and hold a significant share of the certificates.

Based on current information, the EC expects 20 NBs to be designated before the end of this year.

And although the number of NBs under the new regulations could be lower when compared to now (Lloyd's Register Quality Assurance (LRQA) said Wednesday that it will not apply to be an NB under MDR/IVDR), Andriukaitis said: "This is not a surprise... Stricter requirements have been set to ensure that future notified bodies are fully fit for purpose. On the other hand, this will mean higher capacity in designated notified bodies."

As far as progress achieved so far, Andriukaitis pointed to the preparation of the Eudamed database core modules, which will be functional in line with the deadlines, the establishment of the unique device identifier system and work on implementing acts, including one on expert panels, which he said is close to being finalized.

In terms of postponing the transition period, Andriukaitis said that "any change of rules at this late stage would be unfair to serious operators that have carried efforts to ensure their timely compliance.

https://www.raps.org/news-and-articles/news-articles/2019/6/may-2020-mdr-deadline-is-realistic-and-achievable?utm_source=MagnetMail&utm_medium=Email%20&utm_campaign=RF%20Today%20|%2014%20June

https://video.consilium.europa.eu/en/webcast/b35e4b01-00ea-48cc-8937-a93461278b60

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Another Notified Body Bows Out Ahead of EU MDR: 'Investment Too High'

Posted 18 June 2019 | By Zachary Brennan

Swiss notified body (NB) QS Zürich AG has decided that it will not pursue designation under the new EU medical devices regulation (MDR), although EN ISO 13485 support will remain.

Ursula Roesler, head of medical devices at QS Zürich AG, told *Focus* that the medical device department will be closed by the end of October. As far as why the decision was made, Roesler said, "It was a business decision of the CEO—the investment was too high for a small NB like QS Zürich AG."

The company has worked as an accredited certification body for management systems and as an NB for medical devices in the EU since 1998.

The news from Switzerland follows a decision from London-based Lloyd's Register Quality Assurance (LRQA) last week to withdraw its NB services under the EU's current medical device and *in vitro* diagnostic directives and to not apply to be an NB under the new MDR or the *in vitro* diagnostic regulation (IVDR).

LRQA directed clients to choose an alternative NB and the firm established a team to help with transition activities, with the goal of minimizing the risk of disruption.

Similarly, the Spanish Agency of Medicines and Medical Products (AEMPS), the only Spanish NB, said in late May that it will no longer accept device applications from new clients for CE marking and cease to process new certificate applications from existing clients beginning 31 July 2019.

https://www.raps.org/news-and-articles/news-articles/2019/6/another-notified-body-bows-out-ahead-of-eu-mdr-i?utm_source=MagnetMail&utm_medium=Email%20&utm_campaign=RF%20Today%20|%2018%20June

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CONTENT

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- MDR/IVDR – Update with impact for different stakeholders
  - Scope
  - Classification and conformity assessment
  - Designation of Notified Bodies
  - Clinical evaluation
  - Transparency and traceability
  - Activities to prepare MDR/IVDR implementation: Legislation, Guidance, Standards
  - Future regulatory challenges and needs
- National implementation activities
- Conclusions

Regulatory Requirements for IVDMD

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~~EU-Directives~~

~~90/385/EEC 93/42/EEC 98/79/EC~~

Directive 90/385/EEC
- COUNCIL DIRECTIVE of 20 June 1990 on the approximation of the laws of the Member States relating to **active implantable medical devices**

Directive 93/42/EEC
- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning **medical devices**

Directive 98/79/EC
- DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on **in vitro diagnostic medical devices**

MPG – Medizinproduktegesetz

EU-Regulations

MDR

Regulation (EU) 2017/745
Medical Device Regulation

IVDR

Regulation (EU) 2017/746
IVD Medical Device Regulation

Regulatory Requirements for IVDMD

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Directive 90/385/EEC

- COUNCIL DIRECTIVE of 20 June 1990 on the approximation of the laws of the Member States relating to **active implantable medical devices**

The CE marking indicates the conformity of the product with the Union legislation applying to the product and providing for CE marking. — The CE marking is affixed on products that will be placed on the EEA and Turkish market.

EU-Regulations

MDR

Regulation (EU) 2017/745
Medical Device Regulation

IVDR

Regulation (EU) 2017/746
IVD Medical Device Regulation

New Approach and Standardization in the EU

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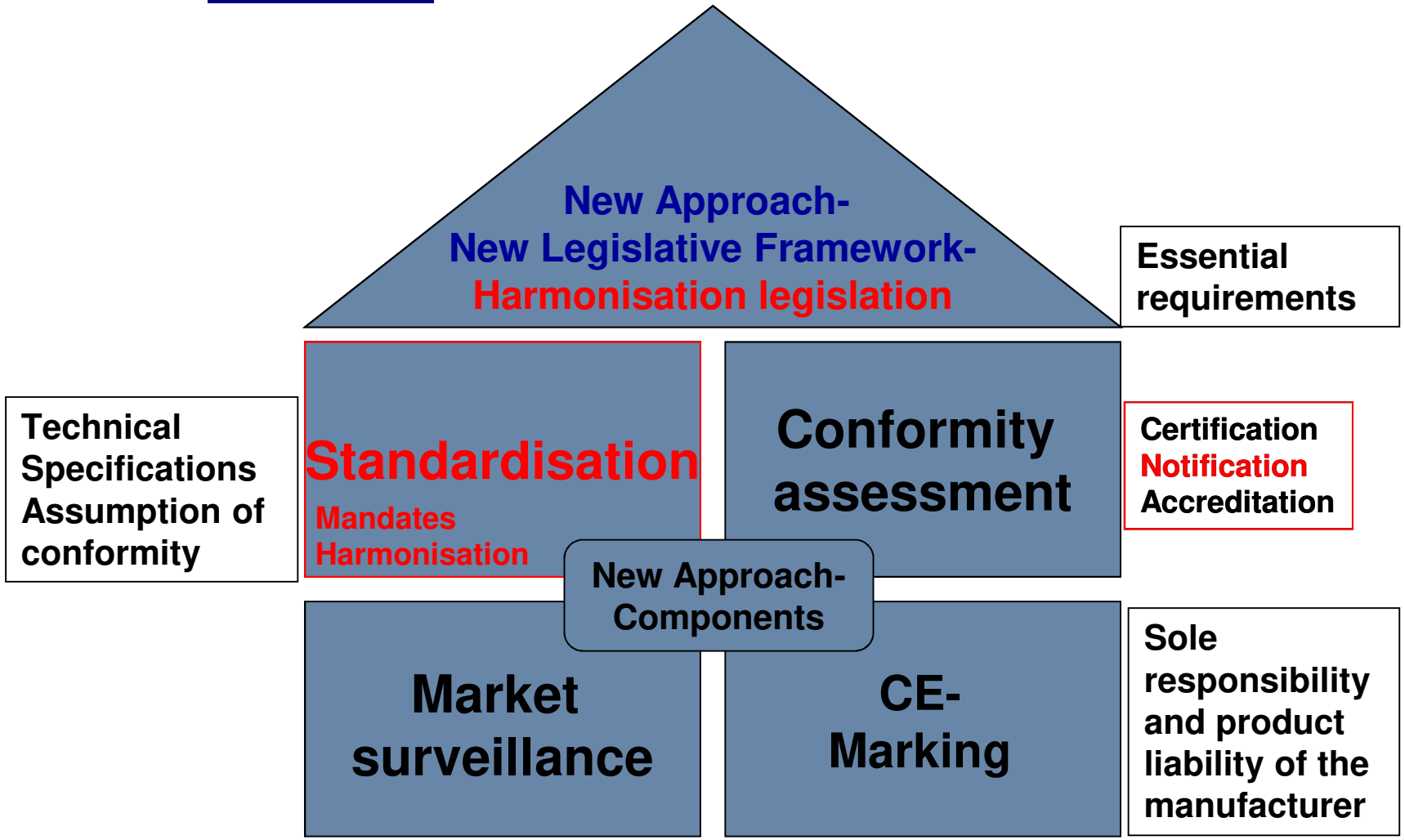

Compare: KAN-Report 47, 2011: „Accreditation of conformity assessment bodies“

MDR/IVDR: Major elements addressed

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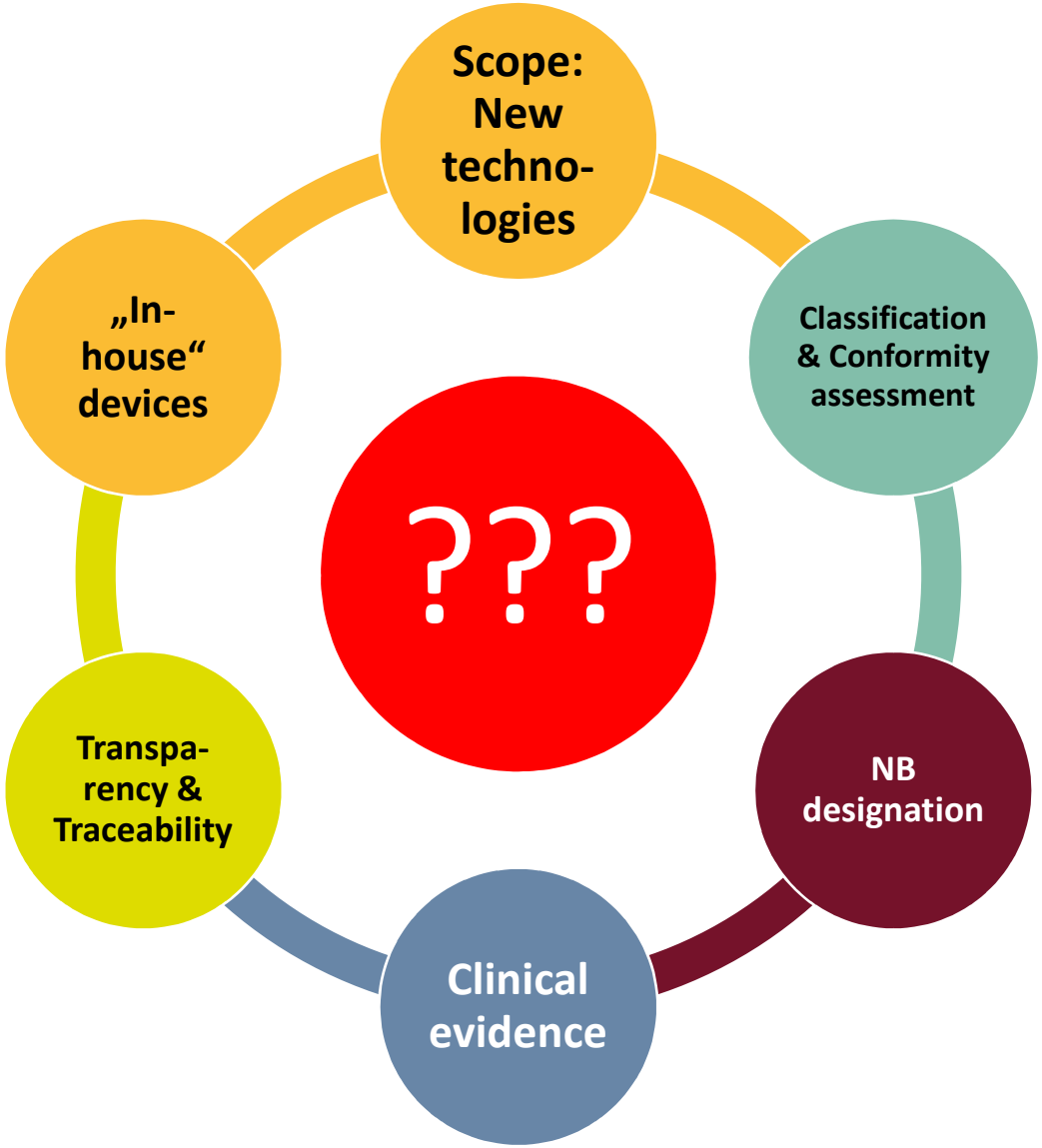

MDR – SCOPE

- ✓ **Nanomaterials:**
  - ✓ MDR Article 2 (18), Annex I (10.6), Annex VIII, Rule 19, Commission Recommendation 2011/696/EU
- ✓ **Substance-based medical devices:**
  - ✓ MDR Annex VIII, Rule 21, Annex I, 12.2
- ✓ **Software:**
  - ✓ MDR Annex VIII, Rule 11
- ✓ **Reusable surgical instruments (Class Ir)**
  - ✓ MDR Article 52 (7)
- ✓ …

MDR – SCOPE

Article 17 Single-use devices and their reprocessing

"1. Reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with this Article. …"

Compliance with Common specifications (CS) for reprocessing of single-use devices to be adopted by the Commission until May 26, 2020

Definition: „single-use device" means a device that is intended to be used on one individual during a single procedure;
MDR, Article 2 (8)

IVDR – Scope

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Extensions and clarifications of the scope of the IVDR concern:

- ✓ **Companion diagnostics**
- ✓ **Near patient testing (POCT)**
- ✓ **Genetic testing**
- ✓ **Medical Software**
- ✓ **In-house devices**
- ✓ **…**

REVIEW Open Access

Precision medicine becomes reality—tumor type-agnostic therapy

Li Yan[1,2*] and Wei Zhang[1,3]

Abstract

Precision medicine just witnessed two breakthroughs in oncology in 2017. Pembrolizumab (Keytruda), Merck's anti-programmed cell death-1 (PD-1) monoclonal antibody (mAb), received accelerated approval in May 2017 by the US Food and Drug Administration for the treatment of adult and pediatric patients with unresectable or metastatic solid tumors that have been identified as having microsatellite instability-high (MSI-H) or deficient DNA mismatch repair (dMMR). Shortly after, nivolumab (Opdivo), Bristol-Myers Squibb's anti-PD-1 mAb, gained an accelerated approval in August 2017 for adult and pediatric patients with MSI-H or dMMR metastatic colorectal cancer that has progressed after standard chemotherapy. These regulatory approvals marked an important milestone that a cancer treatment may be approved based on a common biomarker rather than the anatomic location in the body where the tumor originated, and therefore established a precedent for tumor type-agnostic therapy. In the 2017 American Society for Clinical Oncology annual meeting, larotrectinib (LOXO-101), Loxooncology's oral, potent, and selective inhibitor of tropomyosin receptor kinases (TRK), demonstrated unprecedented efficacy on unresectable or metastatic solid tumors with neurotrophic tropomyosin receptor kinase (NTRK)-fusion proteins in adult and pediatric patients. Both the anti-PD-1 mAbs and the TRK-targeting therapies share some basic features: (a) biomarker-based, well-defined rare patient population; (b) exceptionally high clinical efficacy, e.g., near 40% overall response rate (ORR) for pembrolizumab across 15 tumor types with MSI-H/dMMR and 75% ORR for larotrectinib across more than 12 tumor types with NTRK-fusion proteins; (c) durable responses lasting at least 6 months with complete responses observed; and (d) parallel development in adult and pediatric populations. With increasing accessibility to genetic analysis tools such as next-generation sequencing, tumor type-agnostic therapy has become a reality, both during clinical development and in clinical practice. Adjustments in our approaches to developing new anti-cancer drugs and to adopting these new cancer treatments in clinical practice need to occur in order to prepare ourselves for the new era of precision medicine.

Keywords: Precision medicine, Anti-programmed cell death-1, Microsatellite instability-high, Deficient DNA mismatch repair

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Yan and Zhang *Cancer Commun (2018) 38:6*
https://doi.org/10.1186/s40880-018-0274-3

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Prof. Dr. Folker Spitzenberger

IVDR – CLASSIFICATION & CONFORMITY ASSESSMENT

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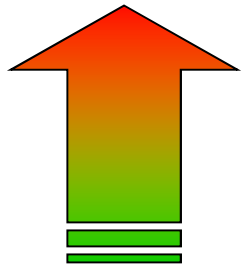
EU Categorisation (98/79/EC)	Devices for the detection/determination/quantification of …	Risk estimation	Degree of quality assurance	GHTF and NEW EU-IVDR, Annex VIII
Annex II, List A	ABO system, rhesus (C, c, D, E, e), anti-Kell, HIV infection (HIV 1 and 2), HTLV I and II, and Hepatitis B, C and D	**High public health risk, high individual risk**	**Full quality assurance**	**Class D**
Annex II, List B	blood groups: anti-Duffy and anti-Kidd, … , rubella, toxoplasmosis, … device for self-diagnosis: blood sugar	**Moderate public health, high individiual risk**		**Class C**
Devices for self testing 	„ any device intended by the manufacturer to be able to be used by lay persons in a home environment.“	**Moderate individual risk for users and/or patients**		**Class B, C** 
Others	Any device.	**Low individual risk, no or minimal public health risk**	**Basic principles and requirements of quality assurance**	**Class A, B, C**

CAVE: There is no 100% comparability of device classes between the different regulation systems.

IVDR: Conformity assessment procedures for CDxs:

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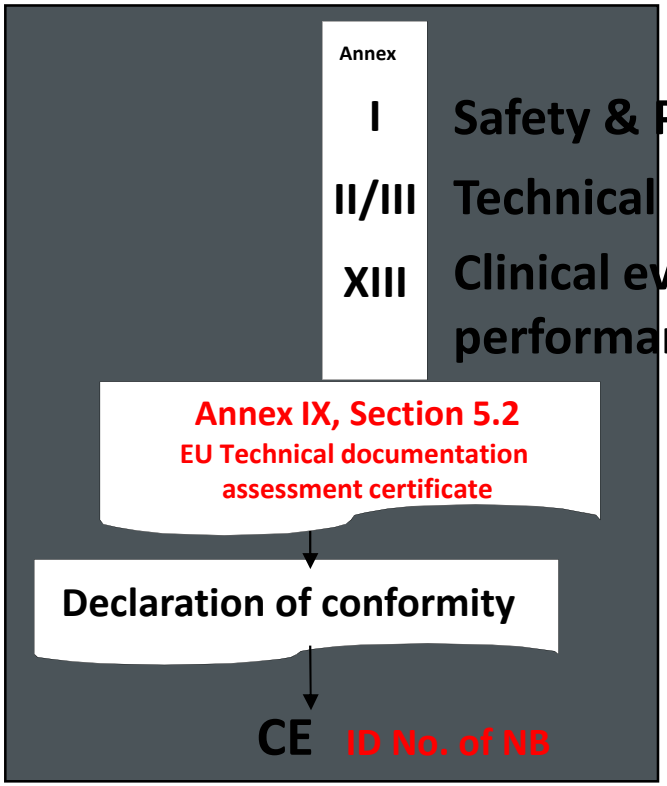
- **Minimum requirements: Annex VIII, Rule 3: CDxs are classified as Class C**



Scientific opinion by medicinal products' competent authority or by EMA
Technical documentation assessment by Notified Body = NB

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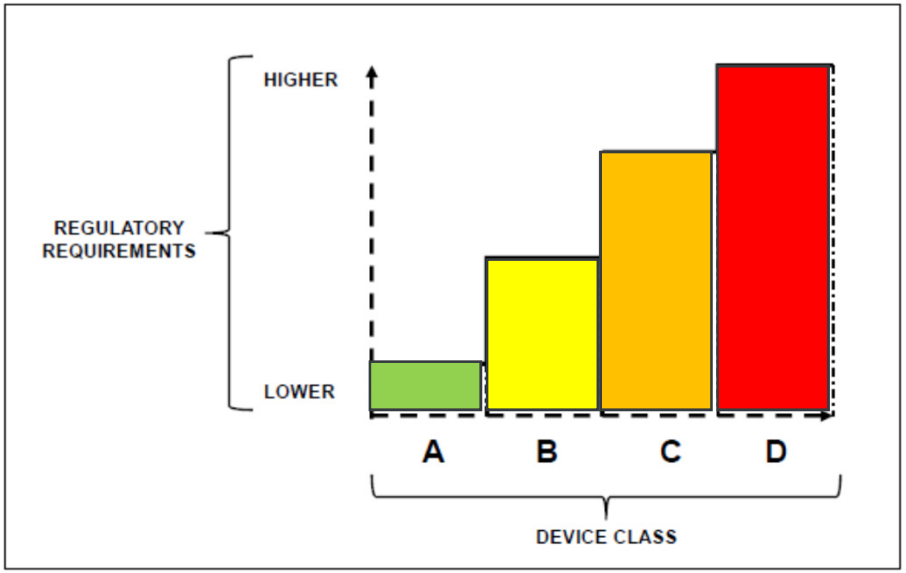
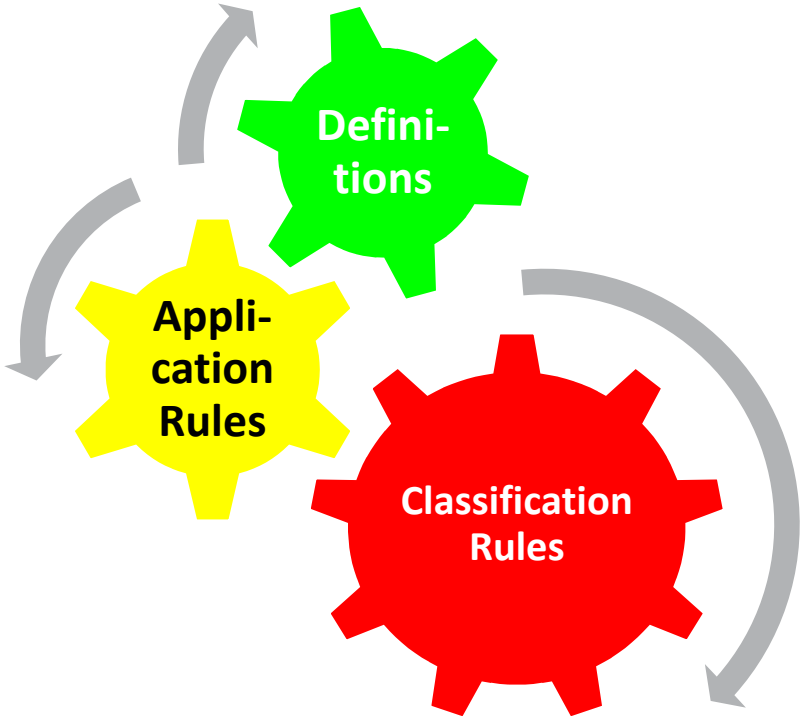


From: WHO GLOBAL MODEL REGULATORY FRAMEWORK FOR MEDICAL DEVICES INCLUDING IVD MEDICAL DEVICES *(May 2017)*

Classification Rules – IVDR, Annex VIII



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"… For IVDs, the biggest change concerns the new risk-based classification of *in vitro* diagnostic devices and the role of Notified Bodies. …

As a result, around 85 % of all IVDs will need Notified Body oversight under the IVDR, compared to 20 % previously under the IVDD (IVDR Article 48). …"

From: European Commission: Factsheet for healthcare professionals and health institutions. Medical Devices: Change of Legislation What you need to know! 05/06/2019

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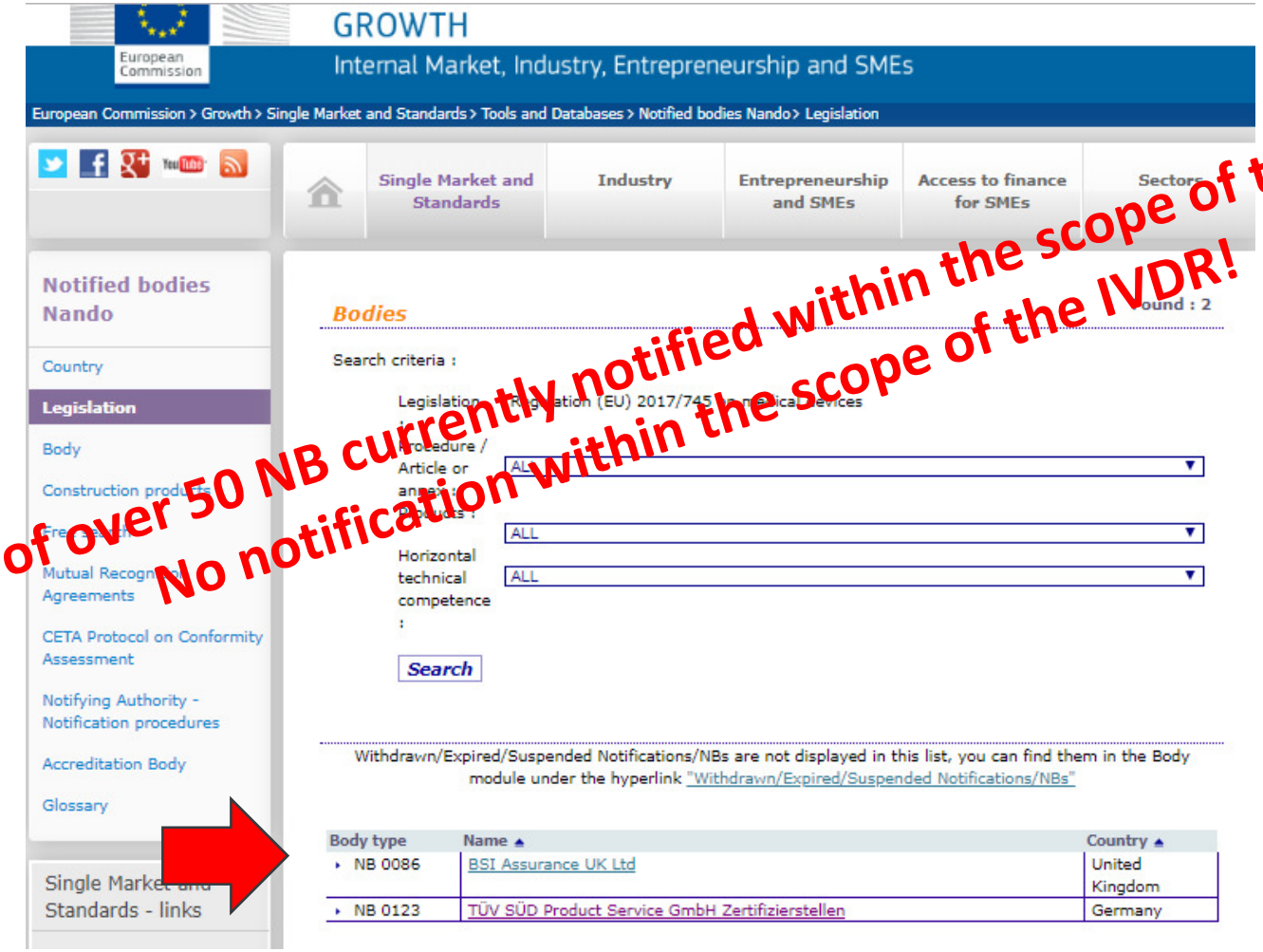
Urgent:

Designation, Capacities and Competence of Notified Bodies



2 out of over 50 NB currently notified within the scope of the MDD!

No notification within the scope of the IVDR!

APPLICATIONS

Last update: April 2019

- Sent to SANTE/F:
  - 38 – MDR
  - 9 – IVDR

  47
- Scope coverage: overall, the entirety of MD and IVD codes

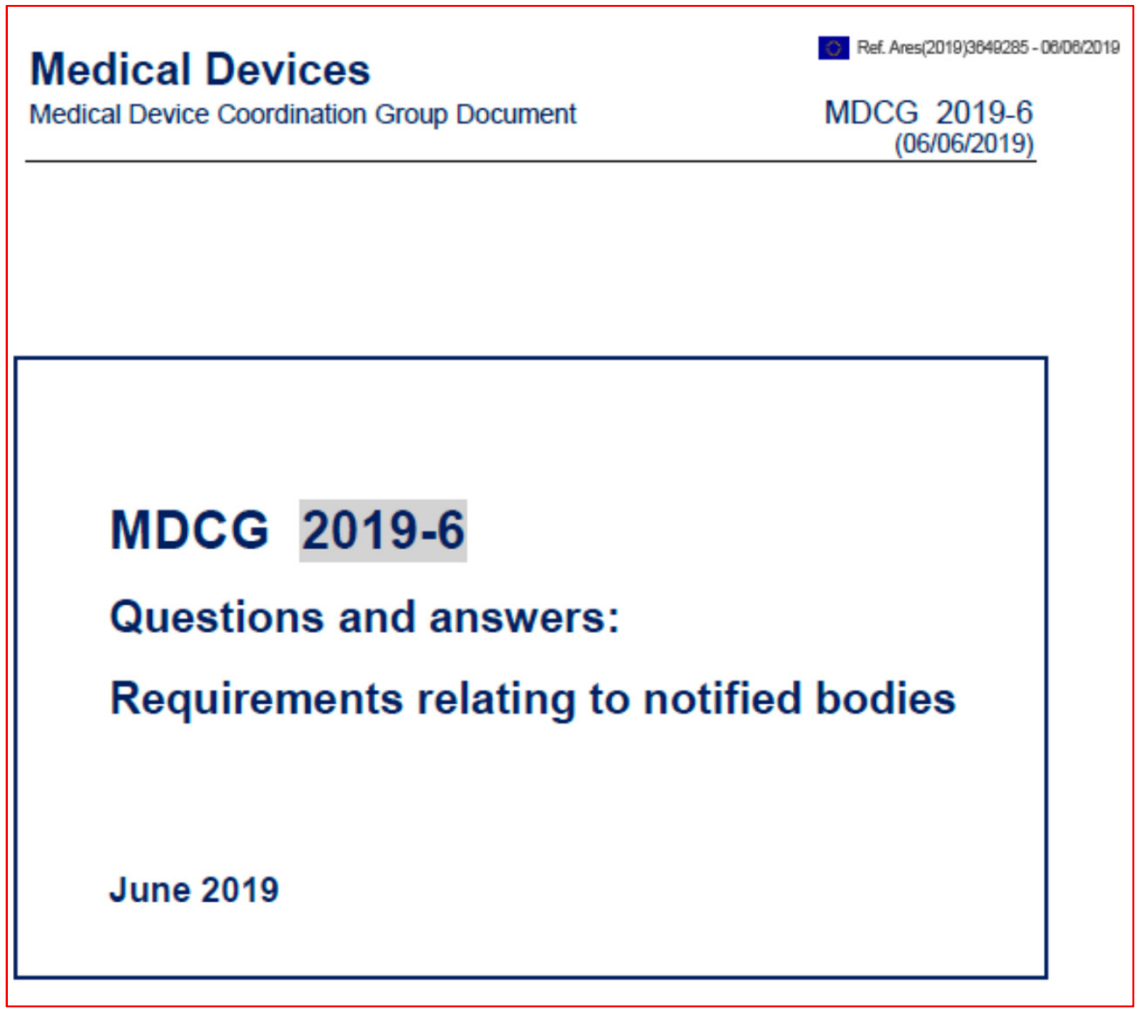
POST-ASSESSMENT ACTIVITIES

- **11** CAPA plans received by SANTE/F
  - **7 JAT opinions issued**
  - **1 CAPA plans undergoing official translation**
  - **3 JAT opinions under preparation**
- **2** Designating authorities' final reports received
  - **2 JAT opinion issued**
  - **1 MDCG recommendation**

5

Health and Food Safety

Weblink: https://ec.europa.eu/docsroom/documents/35043



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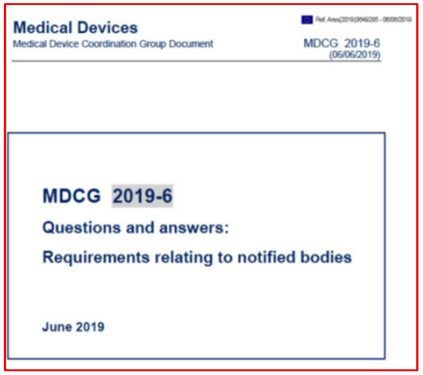
- **Organisation**
- **Independence**
- **QMS**
- **Staff availability and competence**
- **Certification process**
- **…**



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I.7. Can the CAB accept applications prior to being notified?

No, applications under the MDR / IVDR cannot be accepted before the designation of the CAB became valid, i.e. the day after the notification is published in NANDO.

IV.1. Do devices certified under the Directives need to be subject to a full conformity assessment under the new Regulations if the manufacturer applies for certification under the MDR / IVDR?

The **conformity assessment activities** described under Article 52 / Article 48 **apply to any certificate issued under the new regulations**. As **no exceptions were established** under the regulations for the migration or transfer of MDD/AIMDD/IVDD certificates to the MDR / IVDR the general provisions should apply.

COCIR, the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

Medical Device Regulation – One Year to Go

COCIR Recommendations

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- To **limit the initial certification to the Quality Management System (QMS)** and a certain sampling of certain device classes **at initial MDR certification assessment**
- To **participate in the MDSAP program** and to accept MDSAP certificates in the EU in order to relieve Notified Body capacity
- To establish a **EU-wide contingency plan for manufacturers in need of a NB**
- To allow manufacturers of **MDD class I devices to make use of the "grace period"**
- To publish **guidance on (significant) changes** (Article 120 (3)) to clarify whether MDD certificates remain valid following changes that are unrelated to design or intended purpose of the device in question

Clinical Evaluation and the MDR

Factors relevant to clinical evaluation:

- **Justification and specification to the level of clinical evidence** taking into account the characteristics and the intended purpose of the device
- **Definition of equivalence** and **integration of the equivalence concept**
- **Incorporation of PMS data**
- **Acceptability of the benefit-risk ratio** must be based upon sufficient clinical data and linked to the post-market surveillance system
- **Consideration of available alternative treatment options**

Clinical evaluation and the IVDR

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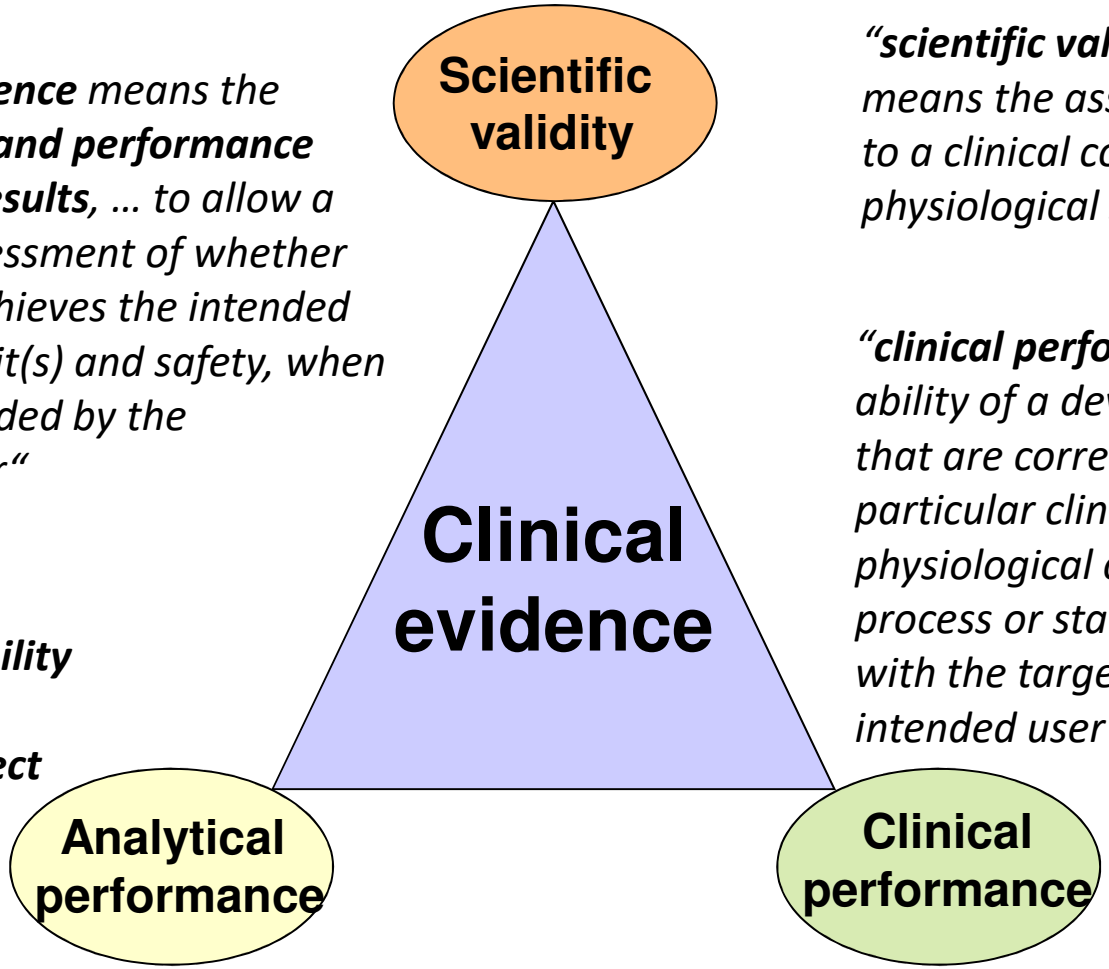
*"**clinical evidence** means the **clinical data and performance evaluation results**, … to allow a qualified assessment of whether the device achieves the intended clinical benefit(s) and safety, when used as intended by the manufacturer"*

*"**analytical performance** means the **ability** of a device **to correctly detect** or measure a particular analyte"*



*"**scientific validity** of an analyte means the association of an analyte to a clinical condition or a physiological state"*

*"**clinical performance** means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user"*

Compare IVDR, Article 56ff, Annex XIII

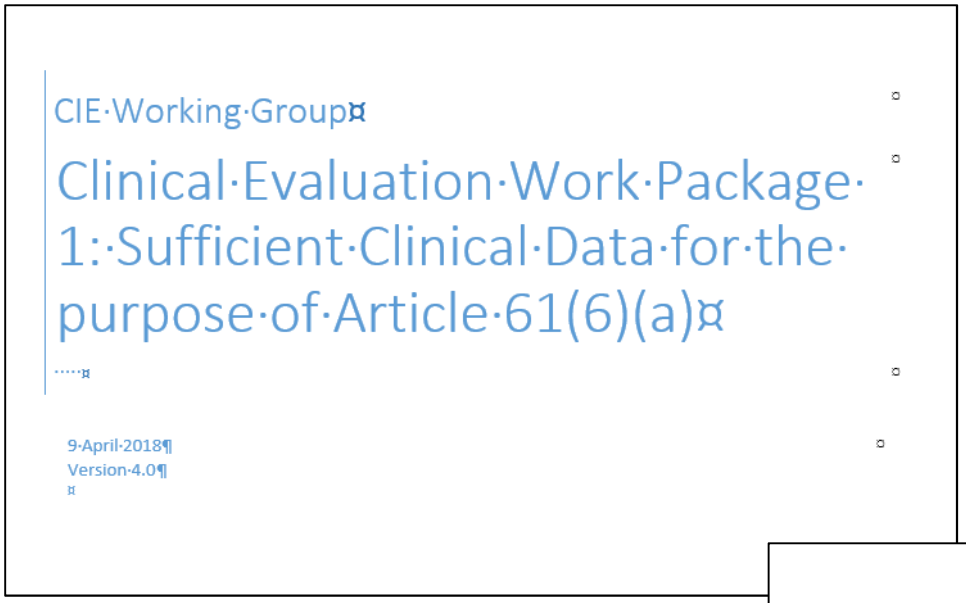
MDCG Subgroups

Details | Additional Information | Meetings | Subgroups | Statistics | Members

Name: Medical Device Coordination Group (X03565) **Active**

Name	Duration	Status
03 - Clinical Investigation and Evaluation (CIE)	permanent	Active
11 - In vitro Diagnostic Medical Devices (IVD)	permanent	Active
04 - Post-Market Surveillance and Vigilance (PMSV)	permanent	Active
05 - Market Surveillance	permanent	Active
01 - Notified Bodies Oversight (NBO)	permanent	Active
06 - Borderline and Classification (B&C)	permanent	Active
02 - Standards	permanent	Active
07 - New Technologies	permanent	Active
12 - Annex XVI		Active
09 - Unique Device Identification (UDI)	permanent	Active
10 - International Matters	permanent	Active

http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3565



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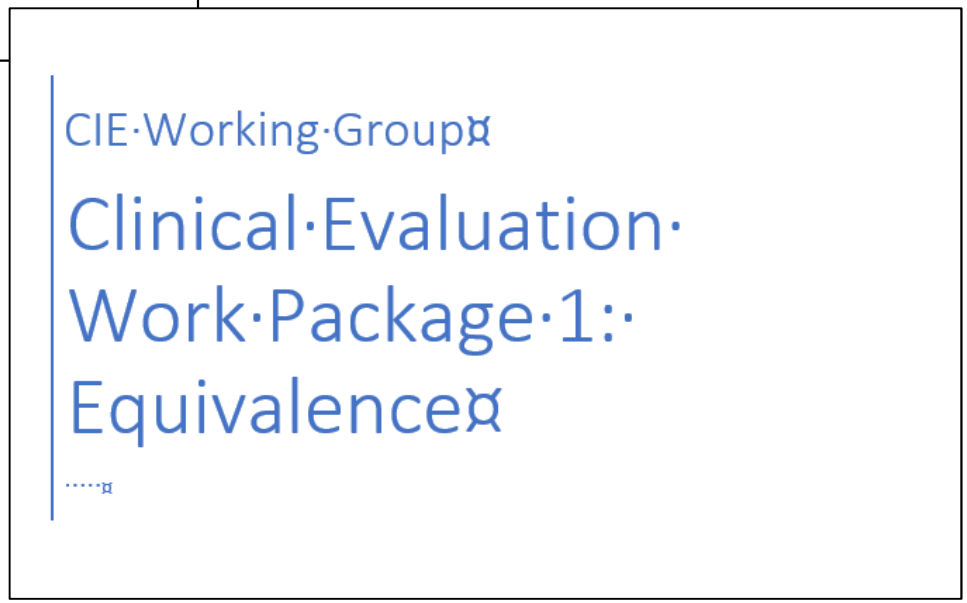
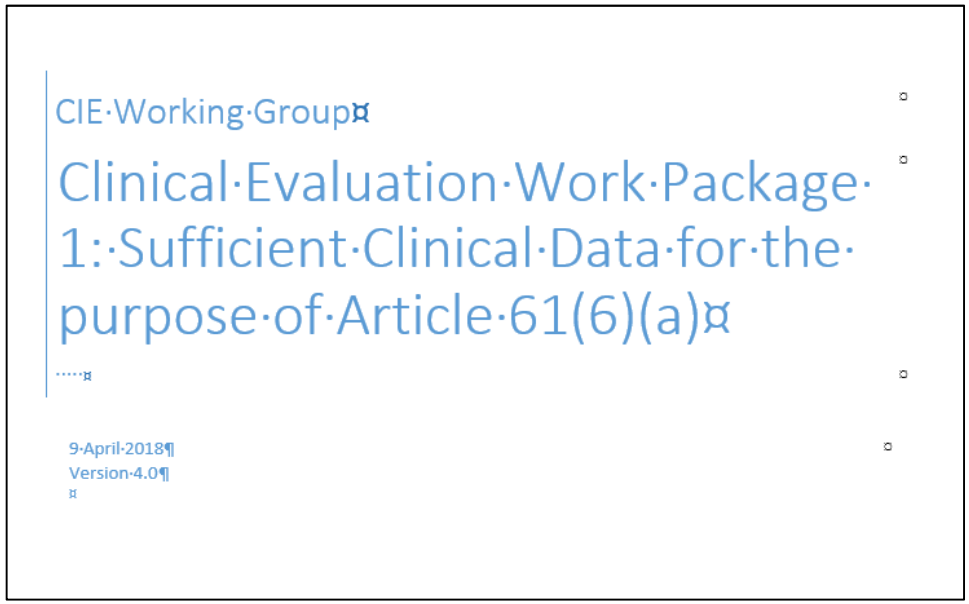
CAVE:
IVDMD NOT covered by the scope of these draft guidelines!





"This guidance **supplements Stage 3 of MEDDEV 2.7/1 Revision 4 – the analysis stage**. It is anticipated that **MEDDEV 2.7/1 Revision 4 may be revised** to take account of the MDR in future. This guidance is therefore interim, and intended to facilitate manufacturers and notified bodies who are preparing for MDR requirements."

"… The **requirement to perform clinical investigations** pursuant to paragraph 4 **shall not apply to implantable devices and class III devices**:

(a) which have been lawfully placed on the market or put into service in accordance with Directive 90/385/EEC or Directive 93/42/EEC and **for which the clinical evaluation**:

— **is based on sufficient clinical data**, …"

from: CIE Working Group: „Equivalence“

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Clinical equivalence

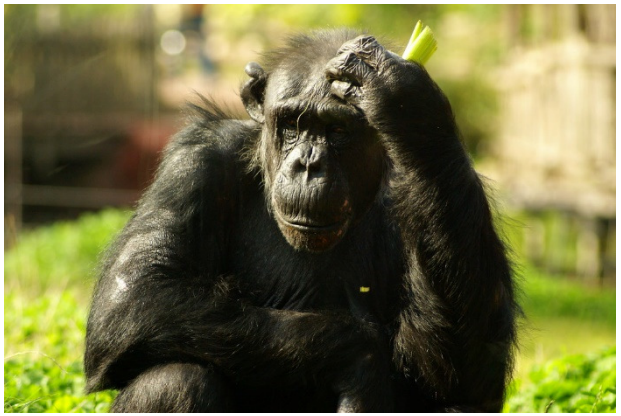
Regulation 2017/745	MEDDEV 2.7/1 rev 4
The device is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.	- used for the same clinical condition (including when applicable similar severity and stage of disease, same medical indication), and - used for the same intended purpose, and - used at the same site in the body, and - used in a similar population (this may relate to age, gender, anatomy, physiology, possibly other aspects), and - not foreseen to deliver significantly different performances (in the relevant critical performances such as the expected clinical effect, the specific intended purpose, the duration of use, etc.)

Technical equivalence

Regulation 2017/745	MEDDEV 2.7/1 rev 4
The device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements.	- be of similar design, and - used under the same conditions of use, and - have similar specifications and properties (e.g. physicochemical properties such as type and intensity of energy, tensile strength, viscosity, surface characteristics, wavelength, surface texture, porosity, particle size, nanotechnology, specific mass, atomic inclusions such as nitrocarburising, oxidability), and - use similar deployment methods (if relevant), and - have similar principles of operation and critical performance requirements

Biological equivalence

Regulation 2017/745	MEDDEV 2.7/1 rev 4
The device uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables	Use the same materials or substances in contact with the same human tissues or body fluids.



Dieses Foto von Unbekannter Autor ist lizenziert gemäß CC BY.

CAVE:

IMDRF: (Justifyable) Comparable device

MDR/MDCG: Equivalent device

MDD: Similar device

Transparency & Traceability:
Nomenclature according to MDR/IVDR requirements

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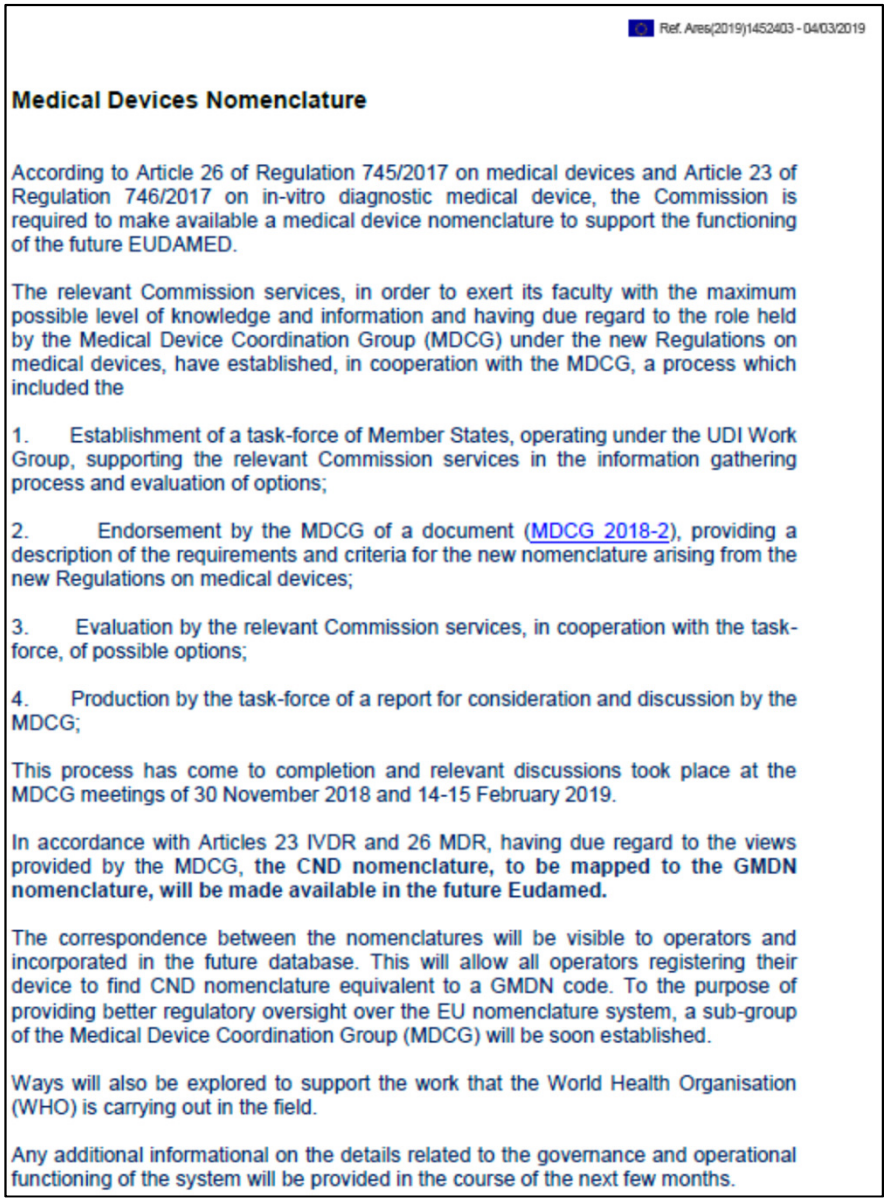
MDCG 2018-2
Future EU medical device nomenclature
Description of requirements

Introduction

According to Article 26 of the Regulation 745/2017 on medical devices and Article 23 of Regulation 746/2017 on *in-vitro* diagnostic medical device, the Commission is required to make available a medical device nomenclature to support the functioning of the future EUDAMED.

This document intends to provide a detailed description of requirements and criteria that the future nomenclature is expected to fulfil. This is expected to serve as a reference basis throughout the decision process and will also ensure that all legal and technical issues associated with the future EU medical device nomenclature are properly mapped.



Ref. Ares(2019)1452403 - 04/03/2019

Medical Devices Nomenclature

According to Article 26 of Regulation 745/2017 on medical devices and Article 23 of Regulation 746/2017 on in-vitro diagnostic medical device, the Commission is required to make available a medical device nomenclature to support the functioning of the future EUDAMED.

The relevant Commission services, in order to exert its faculty with the maximum possible level of knowledge and information and having due regard to the role held by the Medical Device Coordination Group (MDCG) under the new Regulations on medical devices, have established, in cooperation with the MDCG, a process which included the

1. Establishment of a task-force of Member States, operating under the UDI Work Group, supporting the relevant Commission services in the information gathering process and evaluation of options;

2. Endorsement by the MDCG of a document (MDCG 2018-2), providing a description of the requirements and criteria for the new nomenclature arising from the new Regulations on medical devices;

3. Evaluation by the relevant Commission services, in cooperation with the task-force, of possible options;

4. Production by the task-force of a report for consideration and discussion by the MDCG;

This process has come to completion and relevant discussions took place at the MDCG meetings of 30 November 2018 and 14-15 February 2019.

In accordance with Articles 23 IVDR and 26 MDR, having due regard to the views provided by the MDCG, **the CND nomenclature, to be mapped to the GMDN nomenclature, will be made available in the future Eudamed.**

The correspondence between the nomenclatures will be visible to operators and incorporated in the future database. This will allow all operators registering their device to find CND nomenclature equivalent to a GMDN code. To the purpose of providing better regulatory oversight over the EU nomenclature system, a sub-group of the Medical Device Coordination Group (MDCG) will be soon established.

Ways will also be explored to support the work that the World Health Organisation (WHO) is carrying out in the field.

Any additional informational on the details related to the governance and operational functioning of the system will be provided in the course of the next few months.

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" …In accordance with Articles 23 IVDR and 26 MDR, having due regard to the views provided by the MDCG, **the CND nomenclature, to be mapped to the GMDN nomenclature, will be made available in the future Eudamed. …"**

https://ec.europa.eu/docsroom/documents/34264?locale=en

TECHNISCHE HOCHSCHULE LÜBECK

Traduzione in lingua inglese dei codici della Classificazione Nazionale Dispositivi Medici

(come modificata dal DM 13.03.2018)

TRADUZIONE IN LINGUA INGLESE DEI CODICI DELLA CLASSIFICAZIONE NAZIONALE DISPOSITIVI MEDICI

(come modificata dal DM 13.03.2018)

Categoria: A	DISPOSITIVI DA SOMMINISTRAZIONE, PRELIEVO E RACCOLTA *DEVICES FOR ADMINISTRATION, COLLECTING AND PICKING*
A	DISPOSITIVI DA SOMMINISTRAZIONE, PRELIEVO E RACCOLTA *DEVICES FOR ADMINISTRATION, COLLECTING AND PICKING*
A01	AGHI *NEEDLES*
A0101	AGHI E KIT PER INFUSIONE E PRELIEVO *INFUSION AND COLLECTING NEEDLES*
A010101	AGHI IPODERMICI *HYPODERMIC NEEDLES*
A01010101	AGHI IPODERMICI PER SIRINGA *HYPODERMIC NEEDLES FOR SYRINGE*
A01010102	AGHI IPODERMICI PER PENNA *HYPODERMIC NEEDLES FOR PEN*
A01010199	AGHI IPODERMICI - ALTRI *HYPODERMIC NEEDLES - OTHERS*
A010102	AGHI A FARFALLA *BUTTERFLY NEEDLES*
A010103	AGHI E KIT PER SISTEMI IMPIANTABILI *NEEDLES AND KIT FOR IMPLANTABLE SYSTEMS*

Activities to prepare MDR/IVDR implementation: Legislation, Guidance, Standards

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COMMISSION IMPLEMENTING DECISION (EU) 2019/939

of 6 June 2019

designating issuing entities designated to operate a system for the assignment of Unique Device Identifiers (UDIs) in the field of medical devices

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2185

of 23 November 2017

on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council

2 Implementing Acts published

At least 16 further Implementing Acts are required …

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MDR/IVDR Corrigenda

Council of the European Union

Brussels, 13 March 2019

15409/1/18
REV 1

Interinstitutional File:
2012/0266 (COD)

JUR 598
PHARM 68
SAN 460
MI 978
COMPET 864
CODEC 2288

LEGISLATIVE ACTS AND OTHER INSTRUMENTS: CORRIGENDUM/RECTIFICATIF

Subject: 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

(Official Journal of the European Union L 117 of 5 May 2017)

Council of the European Union

Brussels, 13 March 2019

15418/1/18
REV 1

Interinstitutional File:
2012/0267 (COD)

JUR 599
PHARM 69
SAN 461
MI 979
COMPET 865
CODEC 2290

LEGISLATIVE ACTS AND OTHER INSTRUMENTS: CORRIGENDUM/RECTIFICATIF

Subject: 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

(Official Journal of the European Union L 117 of 5 May 2017)

Conclusions:

Total of 10 – 15 corrections (dependent of the language) per Regulation

➡ **Mostly editorial corrections**

➡ **Few technical changes**
(Integration of NB staff, ISO 20916, …)

➡ **Many more unresolved issues, mostly editorial …**

Activities to prepare MDR/IVDR implementation: Legislation, Guidance, Standards

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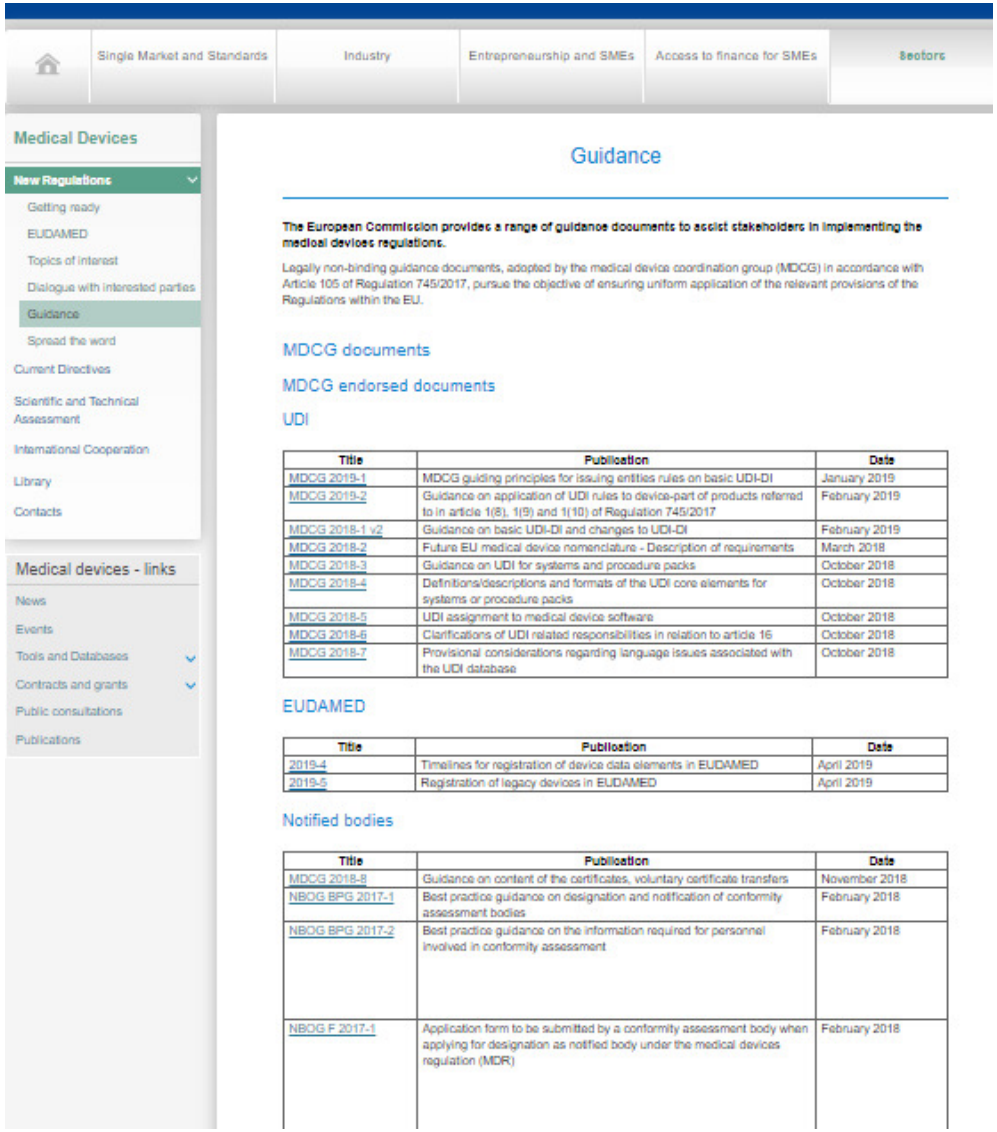
- **Some guidance done**
- **Many topics not yet covered such as critical classification issues, specific conformity assessment requirements (software, reprocessing of single-use devices, nanomaterials, etc.), …**
- **No CS published**



Single Market and Standards | Industry | Entrepreneurship and SMEs | Access to finance for SMEs | Sectors

Medical Devices

New Regulations
- Getting ready
- EUDAMED
- Topics of interest
- Dialogue with interested parties
- Guidance
- Spread the word

Current Directives

Scientific and Technical Assessment

International Cooperation

Library

Contacts

Medical devices - links
- News
- Events
- Tools and Databases
- Contracts and grants
- Public consultations
- Publications

Guidance

The European Commission provides a range of guidance documents to assist stakeholders in implementing the medical devices regulations.

Legally non-binding guidance documents, adopted by the medical device coordination group (MDCG) in accordance with Article 105 of Regulation 745/2017, pursue the objective of ensuring uniform application of the relevant provisions of the Regulations within the EU.

MDCG documents

MDCG endorsed documents

UDI

Title	Publication	Date
MDCG 2019-1	MDCG guiding principles for issuing entities rules on basic UDI-DI	January 2019
MDCG 2019-2	Guidance on application of UDI rules to device-part of products referred to in article 1(6), 1(9) and 1(10) of Regulation 745/2017	February 2019
MDCG 2018-1 v2	Guidance on basic UDI-DI and changes to UDI-DI	February 2019
MDCG 2018-2	Future EU medical device nomenclature - Description of requirements	March 2018
MDCG 2018-3	Guidance on UDI for systems and procedure packs	October 2018
MDCG 2018-4	Definitions/descriptions and formats of the UDI core elements for systems or procedure packs	October 2018
MDCG 2018-5	UDI assignment to medical device software	October 2018
MDCG 2018-6	Clarifications of UDI related responsibilities in relation to article 16	October 2018
MDCG 2018-7	Provisional considerations regarding language issues associated with the UDI database	October 2018

EUDAMED

Title	Publication	Date
2019-4	Timelines for registration of device data elements in EUDAMED	April 2019
2019-5	Registration of legacy devices in EUDAMED	April 2019

Notified bodies

Title	Publication	Date
MDCG 2018-8	Guidance on content of the certificates, voluntary certificate transfers	November 2018
NBOG BPG 2017-1	Best practice guidance on designation and notification of conformity assessment bodies	February 2018
NBOG BPG 2017-2	Best practice guidance on the information required for personnel involved in conformity assessment	February 2018
NBOG F 2017-1	Application form to be submitted by a conformity assessment body when applying for designation as notified body under the medical devices regulation (MDR)	February 2018

Activities to prepare MDR/IVDR implementation: Legislation, Guidance, Standards

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ISO TR 20416
ISO 20916
…

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ISO TR 20416-#:####(X)

ISO TC 210/SC ##/WG 6

Secretariat: AAMI

Title (Medical devices — Post-market surveillance for manufacturers)

WD s

Warning for WD

This document is not an ISO International Standard. It is
change without notice and may not be referred to as an Int

Recipients of this draft are invited to submit, with their co
which they are aware and to provide supporting document

FINAL DRAFT

INTERNATIONAL STANDARD

ISO/FDIS 20916

ISO/TC 212

Secretariat: ANSI

Voting begins on:
2019-02-11

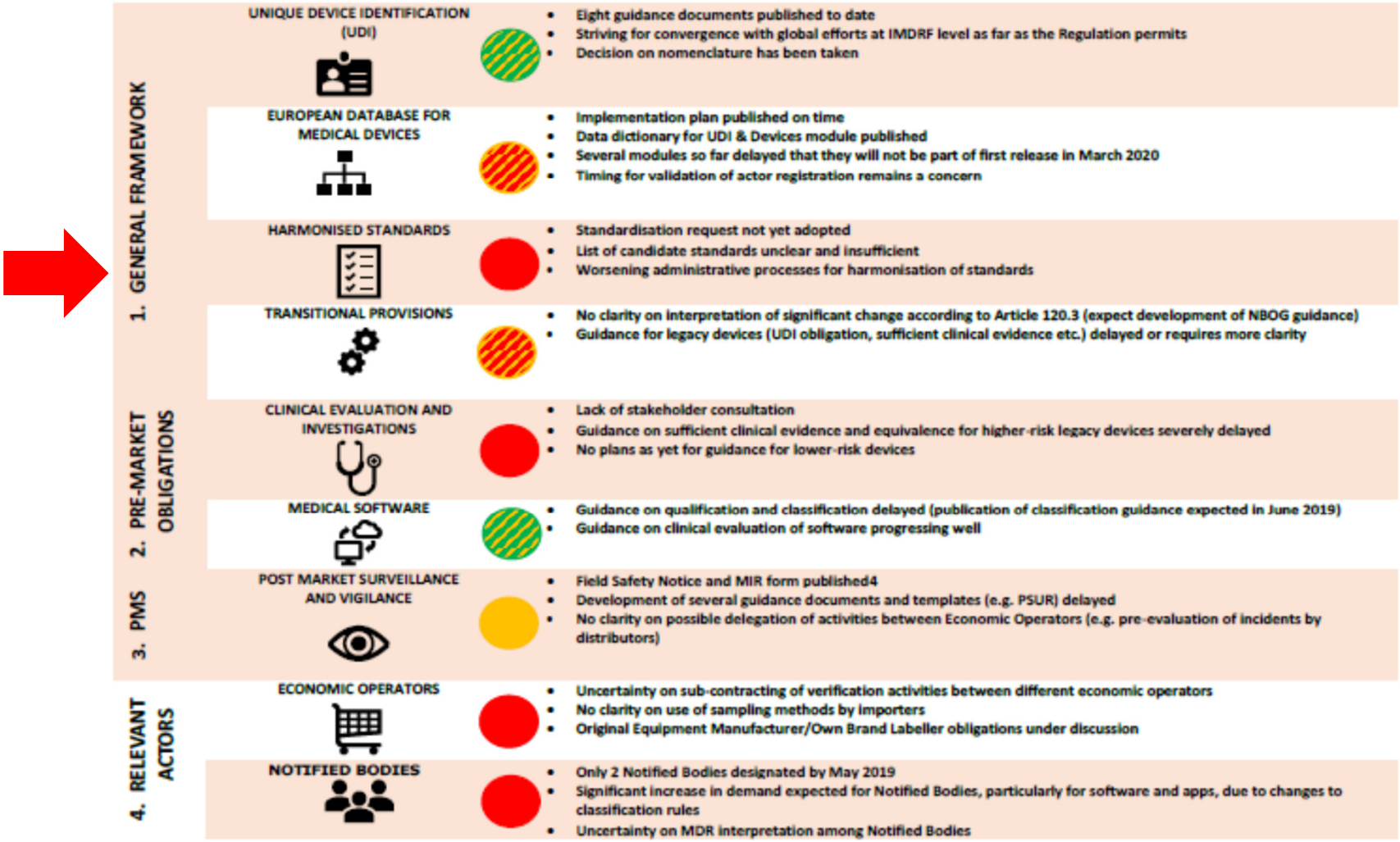
Voting terminates on:
2019-04-08

In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice

Dispositifs médicaux de diagnostic in vitro — Études des performances cliniques utilisant des prélèvements de sujets humains — Bonnes pratiques d'étude

COCIR, the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

Annex: COCIR updated assessment of the MDR's implementation status



1. GENERAL FRAMEWORK	UNIQUE DEVICE IDENTIFICATION (UDI)	• Eight guidance documents published to date • Striving for convergence with global efforts at IMDRF level as far as the Regulation permits • Decision on nomenclature has been taken
	EUROPEAN DATABASE FOR MEDICAL DEVICES	• Implementation plan published on time • Data dictionary for UDI & Devices module published • Several modules so far delayed that they will not be part of first release in March 2020 • Timing for validation of actor registration remains a concern
	HARMONISED STANDARDS	• Standardisation request not yet adopted • List of candidate standards unclear and insufficient • Worsening administrative processes for harmonisation of standards
	TRANSITIONAL PROVISIONS	• No clarity on interpretation of significant change according to Article 120.3 (expect development of NBOG guidance) • Guidance for legacy devices (UDI obligation, sufficient clinical evidence etc.) delayed or requires more clarity
2. PRE-MARKET OBLIGATIONS	CLINICAL EVALUATION AND INVESTIGATIONS	• Lack of stakeholder consultation • Guidance on sufficient clinical evidence and equivalence for higher-risk legacy devices severely delayed • No plans as yet for guidance for lower-risk devices
	MEDICAL SOFTWARE	• Guidance on qualification and classification delayed (publication of classification guidance expected in June 2019) • Guidance on clinical evaluation of software progressing well
3. PMS	POST MARKET SURVEILLANCE AND VIGILANCE	• Field Safety Notice and MIR form published4 • Development of several guidance documents and templates (e.g. PSUR) delayed • No clarity on possible delegation of activities between Economic Operators (e.g. pre-evaluation of incidents by distributors)
4. RELEVANT ACTORS	ECONOMIC OPERATORS	• Uncertainty on sub-contracting of verification activities between different economic operators • No clarity on use of sampling methods by importers • Original Equipment Manufacturer/Own Brand Labeller obligations under discussion
	NOTIFIED BODIES	• Only 2 Notified Bodies designated by May 2019 • Significant increase in demand expected for Notified Bodies, particularly for software and apps, due to changes to classification rules • Uncertainty on MDR interpretation among Notified Bodies

From: COCIR Recommendations, Medical Device Regulation – One Year to Go, June 6th, 2019

MDR/IVDR-Implementation: Rolling plan

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MDR / IVDR - IMPLEMENTATION ROLLING PLAN

This Rolling Plan contains the list of identified essential implementing acts, actions and guidance to be put in place by the Commission and/or the MDCG during the transitional period together with relevant information on expected timelines and state-of-play. The information is organised into two main sections (implementing acts; other actions/initiatives). The document will be subject to quarterly review in order to provide the authorities and stakeholders with the most updated information. This document shall be read in conjunction with the "MDR/IVDR roadmap", produced by the Competent Authorities for Medical Devices project (CAMD) in cooperation with the Commission (and available at https://www.camd-europe.eu/regulatory/medical-devices-regulation-vitro-diagnostics-regulation-mdr-ivdr-roadmap), which contains a much more comprehensive overview of all the initiatives (including guidance) expected to be undertaken during the transitional period by the Commission and the National Competent Authorities

Latest update: April 2019

No.	Subject	Legal basis	Description	Expected timelines (expected date of final adoption/date of accomplishment)	State-of-play/Next step
			IMPLEMENTING REGULATIONS/ACTS		
1	Notified bodies scope of designation	Article 42(13) MDR Article 38(13) IVDR	Implementing Act Definition of the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation of notified bodies. This action is an essential pre-condition for the launch of the designation procedure for Notified Bodies	26 November 2017 (Legal deadline)	Adopted and published on 24 November 2017 COMPLETED
2	Reprocessing of single-use medical devices	Article 17(5) MDR	Implementing Act Common specifications laying down requirements related to reprocessing of single-use devices concerning: — risk management, including the analysis of the construction and material, related properties of the device (reverse engineering) and procedures to detect changes in the design of the original device as well as of its planned application after reprocessing, — the validation of procedures for the entire process, including cleaning steps, — the product release and performance testing, — the quality management system, — the reporting of incidents involving devices that have been reprocessed, and — the traceability of reprocessed devices.	November 2019 It shall be noted that, in the event that those CS are not adopted by 26 May 2020, reprocessing shall be performed in accordance with any relevant harmonised standards and national provisions	Formal public consultation (Q2 2019)

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Future regulatory challenges and needs

? Personalised medical devices

? Medical devices for children, elderly and rare diseases

? Artificial Intelligence Products

IMDRF – Consultation Documents

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1. **Custom-made medical device**
2. **Patient-matched medical device**
3. **Adaptable medical device**

➡ **Considerations on**

- **3 D printed medical devices,**
- **Point-of-care production of medical devices,**
- **…**

National implementation activities

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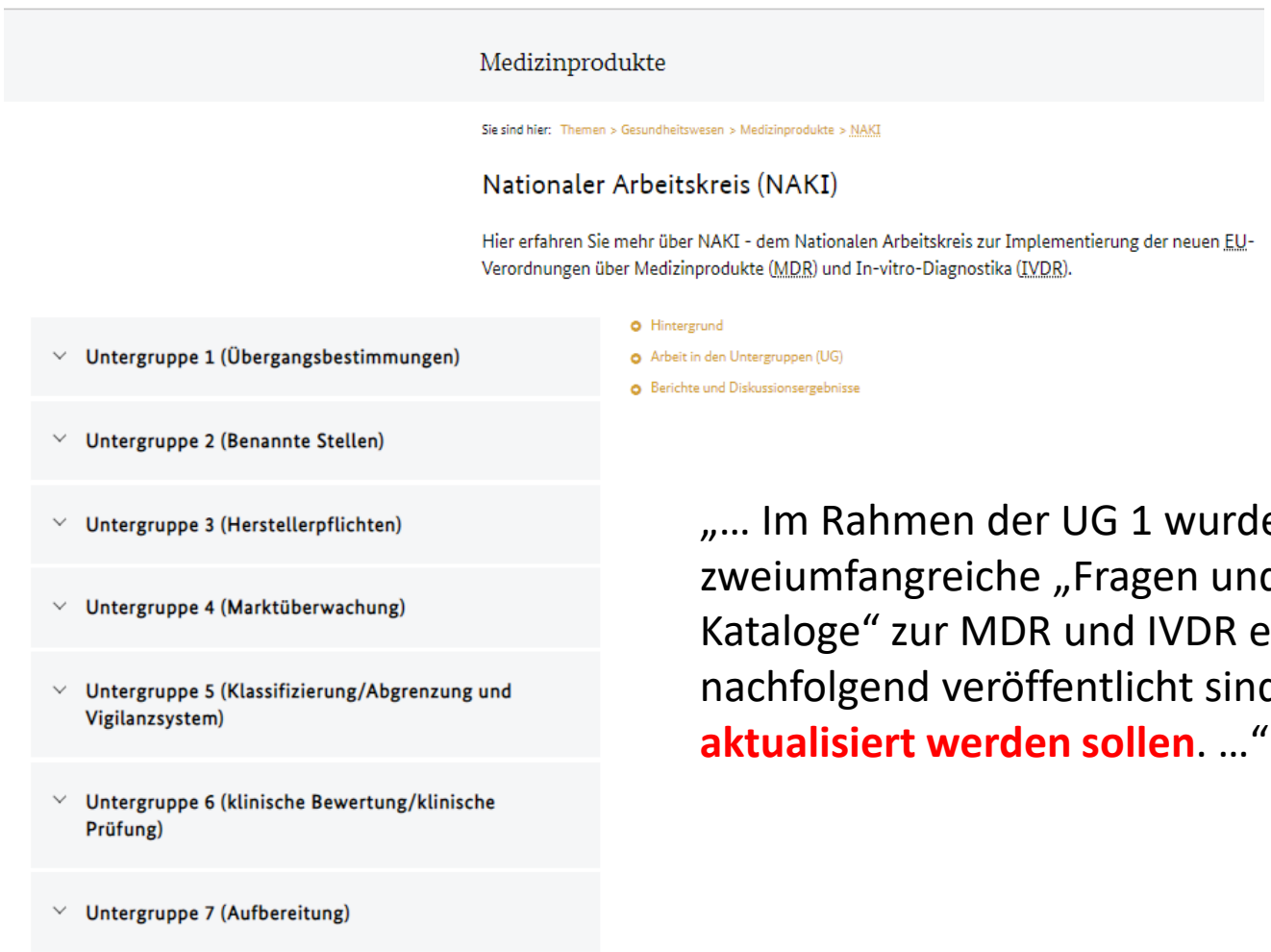

„… Im Rahmen der UG 1 wurden zweiumfangreiche „Fragen und Antworten - Kataloge“ zur MDR und IVDR erarbeitet, die nachfolgend veröffentlicht sind und **stetig aktualisiert werden sollen**. …“

???

National implementation activities*

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- Replacement of the current MPG by the „**Gesetz zur Durchführung unionsrechtlicher Vorschriften betreffend Medizinprodukte und In-vitro-Diagnostika (MIDG)**“ (Date of application: 26.05.2020)
- For IVD: MPG will remain valid for 2 more years (until 26.05.2022)
- MIDG will be introduced by a „Gesetz zur Anpassung des Medizinprodukterechts an die Verordnung (EU) 2017/745 (MDR) und die Verordnung (EU) 2017/746 (IVDR)“
- National regulations will be either partly deleted (MPV, MPSV, MPKPV) or changed (MPBetreibV) by a „Verordnung zur Anpassung des Medizinprodukterechts an die Verordnung (EU) 2017/745 (MDR) und die Verordnung (EU) 2017/746 (IVDR)“
- The drafts of the new national Act and the regulation are expected to be published at the end of July 2019.

*Information by BMG at the 14th BVMed Symposium, June 12th, 2019

BIOMEDTEC SCIENCE CAMPUS LÜBECK …

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Biomedical Engineering | M.Sc.

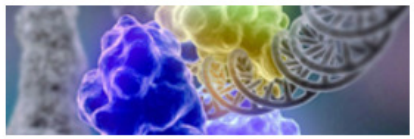
Internationaler Masterstudiengang in Kooperation von der Fachhochschule Lübeck und der Universität zu Lübeck.

Biomedizintechnik | B.Sc.

Bachelorstudiengang der Fachhochschule Lübeck zur Kombination von ingenieurwissenschaftlichen Prinzipien mit medizinischen Fachwissen.

Hörakustik | B.Sc.

Bachelorstudiengang der Fachhochschule Lübeck für ausgebildete Hörakustiker/Hörakustikerinnen zur beruflichen Weiterentwicklung.



Medizinische Informatik | B.Sc., M.Sc.

Bachelor- / Masterstudium an der Universität mit Fokus auf moderne Techniken und Methoden zur computergestützten Informationsverarbeitung in der Medizin

Medizinische Ingenieurwissenschaft | B.Sc., M.Sc.

Bachelor- / Masterstudiengang der Universität zu Lübeck zum Verständnis von medizintechnischen Problemstellungen und deren Lösung.

BIOMEDTEC SCIENCE CAMPUS LÜBECK …

TECHNISCHE HOCHSCHULE LÜBECK

Biomedical Engineering | M.Sc.

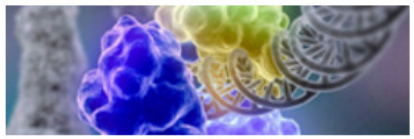
Internationaler Maste
Lübeck und der Unive

Biomedizintec

Bachelorstudiengang
von ingenieurwissens

Hörakustik | B

Bachelorstudiengang
Hörakustiker/Hörakus



Medizinische I

Bachelor- / Masterstu
und Methoden zur co

Medizinische Ingenieurwissenschaft | B.Sc., M.Sc.

Bachelor- / Masterstudiengang der Universität zu Lübeck zum Verständnis von medizintechnischen Problemstellungen und deren Lösung.

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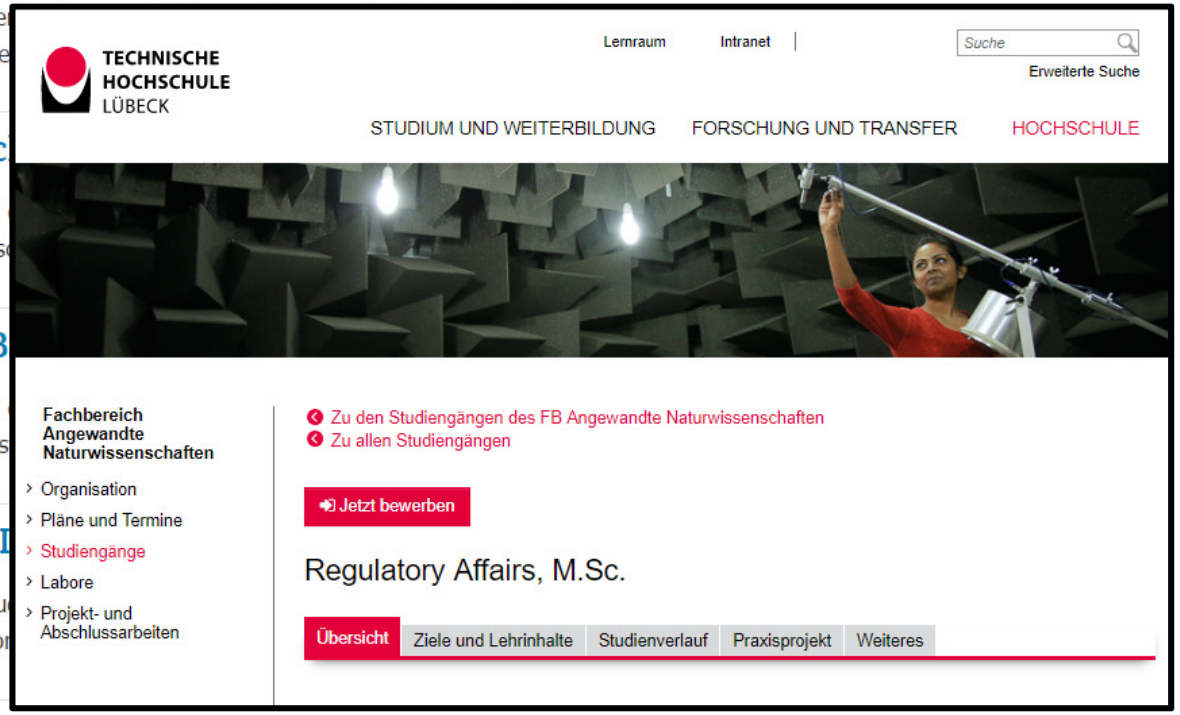

Conclusions - Benefit and Risks

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- ✓ Improved expected patient safety and user protection
- ✓ Increased transparency and harmonization for related stakeholders
- ✓ International comparability of the regulatory framework

- ⚠ Availability and capacities of Notified Bodies
- ⚠ Lack of sufficient guidance and standards
- ⚠ Delay and complication of the marketing process for newly defined, up-classified, changed devices

Many thanks for your attention.

Prof. Dr. Folker Spitzenberger

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