MDR: ask your NBs

Klaus-Dieter, Bassil, Gert
They have the same knowns and unknowns...

- **Rights and responsibilities of stakeholders**
- **Continous improvement**
- **Clinical trials**
- **Non-viable human cells/tissues**
- **QMS & pdca**
- **Traceability**
- **LiABiLiTy**
- **MDCG**
- **Scrubity**
- **Suspension & recalls**
- **Empowerment**
- **Reprocessing**
- **Sud**
- **Hazardous substances**
- **Phthalates**
- **CMR**
- **EU DAMED**
- **PMS PMCF**
- **Reclassification**
- **NBS**
- **COMON SPECIFICATIONS**
- **Trend analysis**
- **The practical approach**
# EU MDR NB designation status – MTE slide from Phil

## NB designation under IVDR/MDR: Overview*

<table>
<thead>
<tr>
<th>Stages of the NB designation procedure</th>
<th>(1) Complete applications received by DG SANTE</th>
<th>(2) Pre-assessment/Off-site activities</th>
<th>(3) On-site assessments</th>
<th>(4) CAPA Plans received by DG SANTE</th>
<th>(5) Applications in Final Designating Steps</th>
<th>Notification in NANDO</th>
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<tr>
<td>Total</td>
<td>47 (≈ 35-40 Notified Bodies)</td>
<td>33</td>
<td>32</td>
<td>11**</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>IVDR</td>
<td>9</td>
<td>6</td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>MDR</td>
<td>38</td>
<td>27</td>
<td>26</td>
<td>9</td>
<td>2 MDCG recommendations</td>
<td>1</td>
</tr>
</tbody>
</table>

*Information based on [Team-NB surveys](https://example.com) and [European Commission information](https://example.com) (Last updated on 23 April 2019)

**7 JAT draft opinions + 3 JAT draft opinions under preparation + 1 CAPA plan undergoing translation

<table>
<thead>
<tr>
<th>Notification in NANDO</th>
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<tr>
<td>11 applications in final stage of designation</td>
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</table>

| 2 MDCG recommendations on applications, awaiting notification in NANDO |

<table>
<thead>
<tr>
<th>8 months + 6-10 months</th>
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<tr>
<td>+ 4-6 weeks</td>
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</table>

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3
ASK THE NOTIFIED BODY MEDCERT
Transition from the MDD to the MDR

Klaus-Dieter Ziel, Managing Director
Friday, 3 May 2019
1. Overview Conformity Assessment Procedure
2. Transition according to article 120
3. Recommendation for a smooth transition
4. Class Ir reusable surgical instruments
Key Message:

- **still 4 risk classes:** I, IIa, IIb, III

- **but new sub-risk classes:**
  - Ir reusable surgical instruments
  - IIb active device to administer and/or remove a medicinal product
  - III implantable, medicinal, human origin, animal origin and absorbed/dispersed

- **which have to undergo a conformity assessment or a specific additional conformity assessment**
Transition according to article 120

**Article 120**

**Transitional provisions**

1. From 26 May 2020, any publication of a notification in respect of a notified body in accordance with Directives 90/385/EEC and 93/42/EEC shall become void.


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

3. By way of derogation from Article 5 of this Regulation, a device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.
Key Message:

- After 26 May 2020, MDD certificates get invalid until the end of the period indicated on the certificate, but latest on 27 May 2024 (attention: annex II (3) and annex II (4)!!)

- .... and only if there is no significant change in the design and intended purpose

- Extremely important question: What is/is not a „significant change in the design and intended purpose“?

No definition in the MDR!! Waiting for guidance documents!
Transition according to article 120

**Article 120**

**Transitional provisions**

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

4. Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2020, and devices placed on the market from 26 May 2020 by virtue of a certificate as referred to in paragraph 2 of this Article, may continue to be made available on the market or put into service until 27 May 2025.
Key Message:

• Notified Body continue to be responsible for appropriate surveillance of MDD certificates

• MDD products placed on the market prior or after 26 May 2020 may continue to be made available on the market or put into service until 27 May 2025

• see article 2 „Definitions“ no. 28: placing on the market
• see article 2 „Definitions“ no. 27: making available
• see article 2 „Definitions“ no. 29: putting into service
Transition according to article 120

Article 2

Definitions

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

(28) ‘placing on the market’ means the first making available of a device, other than an investigational device, on the Union market;

(29) ‘putting into service’ means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;
Recommendation for a smooth transition

A smoooooooth transition ....
Recommendation for a smooth transition

We must avoid situations like this.....
Key Message:

- What is the validity date of your current MDD certificate?
- Be aware, that it is absolutely impossible to transfer to the MDR during the last audit only months before the MDD certificate gets invalid!!
- Start the transition to the MDR (at least) during the audit 1 year before
- Be ready (at least) with your preparation 6 months before the transition audit
- Start with gap analysis/preparation for the transition (at least) 2.5 to 3 years before validity date
Other important topics:

Article 52

Conformity assessment procedures

7. Manufacturers of class I devices, other than custom-made or investigational devices, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III. If those devices are placed on the market in sterile condition, have a measuring function or are reusable surgical instruments, the manufacturer shall apply the procedures set out in Chapters I and III of Annex IX, or in Part A of Annex XI. However, the involvement of the notified body in those procedures shall be limited:

(c) in the case of reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.
Key Message:

- Class Ir reusable surgical instruments need a MDR certificate latest on 26 May 2020!

- Sample representative device and review the technical documentation regarding cleaning, disinfection, sterilisation, maintenance, functional testing and IFUs.

- Audit the QMS for all aspects of the MDR that apply to class Ir devices (e.g. design & development, change control, process validation, training and qualification, purchasing and supplier management, training and internal audits etc.)
No Bottlenecks

😊 33 MDR + 9 IVDR applications were received
😊 Covering all NBOG MD Scopes
😊 Step 1 was finalized for 24 MDR and 6 IVDR applications → Preliminary assessment reports (DA to SANTE/F)

😊 16 MDR Joint Assessments were or will be done till Dec 18
😊 5 IVDR Joint Assessments were or will be done till Dec 18
😊 7 MDR Joint Assessments were or will be done till Week 29
😊 7 CAPA Plans received by SANTE/F
😊 6 MDR Reviews and 1 IVDR Review were issued
😊 1 Recommendation for designation was received
😊 1 Notified Body is designated (BREXIT!!!)

Availability of Notified Bodies at DoA
Waves of projects in the upcoming years
Common understanding documents “Guidance Documents”

When can those documents be available?

Various Task Forces of the EU Commission are working on:

- Guidance and templates for PSURs
- Guidance and template for SSCPs
- Guidance and templates for PMCFs
- Guidance for sufficient clinical data
- Guidance for equivalence approach – Gap Document to MEDDEV 2.7.1 Rev. 4
- Etc.
Moving targets and short timelines – Still approx. 390 days 😞

- Last submissions under the current legislative framework in November 2019
- First MDR application acceptance earliest in late summer 2019
- Expert panels first available in Q3 2019
- EUDAMED go-live in March 2020
- Common specifications for products without medical purpose in November 2019
- New discussion on Brexit in October 2019
- Second Corrigendum in Summer 2019
Open panel debate
Thank you for your attention

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