EU MDR
Timeline

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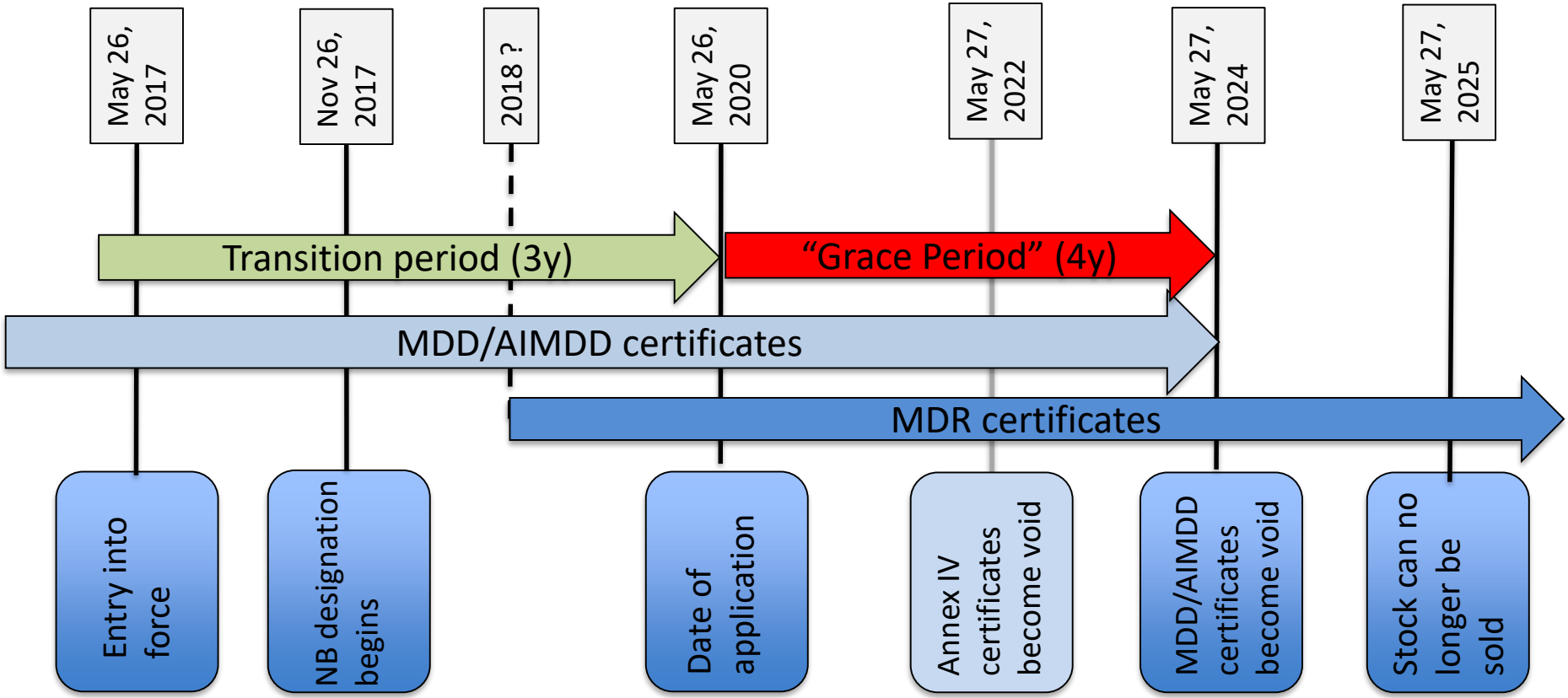
Jones Day

EU MDR - Timeline

- EU has entered into force, but will only apply for products as of May 26, 2020, with transitional period through 2024/2025?
- Look closer!

EU MDR – Timeline - Baseline



EU MDR – Timeline – Product Modifications

- Transition period through 2024 and sell-off through 2025 only applies to products as certified by May 26, 2020.
- Any product modification requiring new conformity assessment has to comply with MDR, if placed on the market after May 26, 2020!

EU MDR – Timeline – Impact of NoBo designation and Brexit

- There will be fewer notified bodies.
- Relocation of UK notified bodies will create extra burden.
- Notified bodies already today flag insufficient capacities.

EU MDR – Timeline – Counting backwards

- If manufacturers plan to modify their products, they should get them certified before May 26, 2020.
- With crunch on notified bodies, complete update to technical file asap and update certification!

EU MDR – Timeline – Looking ahead

- Modified products reaching market only after May 26, 2020 have to meet MDR.
- Potential upclassification!
- Clinical requirements!
- And: notified bodies under new designation!
- [NB: Market surveillance applies as of Day 1]

MDR

Extended Scope and new classification rules

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Extended Scope

Products included **independent of medical purpose**

Art. 1 (2) and Annex XVI MDR

Recital 12: Devices similar to medical devices in terms of functioning and risk profile, but without a medical purpose

MDR applicable to certain products with cosmetic purpose

Non-corrective contact lenses, invasive surgical products for aesthetic surgery (except tattoo and piercing instruments), subcutaneous filling material, equipment for liposuction, high-intensity radiation emitting equipment intended to be used on the human body, cognitive enhancers/brain machines

Extended Scope

- Manufacturers of products listed in Annex XVI shall comply with the common specifications for the respective product Art. 9 (4) MDR
- The European Commission will publish the common specifications for the products listed in the Annex before May 26, 2020. Once published, they will apply after a transition period of 6 months.
- The European Commission is entitled to extend the list of products in Annex XVI. For such products, the Commission will also publish common specifications.
- Applicability of Member State laws that apply to medical devices – for instance with regard to advertising

New classification rules

- Class I devices – self certification without notified body
- Exception: Class I sterile (Is) and Class I with measuring function (Im) require notified body certification with regard to sterility and metrology
- NEW: Class I reusable (class Ir) for reusable surgical instruments
- 22 rules instead of 18, important new Rules 11, 19, 21

Software

- Recital 19

- “It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for **life-style and well-being purposes** is not a medical device. The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.”

Software

- Rule 11

- Software intended to provide information which is used to **take decisions with diagnosis or therapeutic purposes** is classified as class IIa, except if such decisions have an impact that may cause:
- **Death or an irreversible deterioration of a person's state of health**, in which case it is in class III; or
- **Serious deterioration** of a person's state of health or a **surgical intervention**, in which case it is classified as class IIb.
- Software intended to **monitor physiological processes** is classified as class IIa, except if it is intended for **monitoring of vital physiological parameters**, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

- All other software are classified as class I."

Probable Up-classification

Product	MDD risk class	MDR risk class
App for calculation of dosing for cytostatics	I	III
Software suggesting diagnosis based on lab results	I	IIb or III
App for diagnosis of sleep apnea	I	IIa or higher
Patient data management systems (PDMS)	I or IIa	IIb or III

Devices composed of substances

- Rule 21

- Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as:
- — class III if they, or their products of metabolism, are **systemically absorbed by the human body in order to achieve the intended purpose**;
- — class III if they achieve their intended purpose **in the stomach or lower gastrointestinal tract** and they, or their products of metabolism, **are systemically absorbed by the human body**;
- — class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities; and
- — class IIb in all other cases.

Probable Up-classification

Product	MDD risk class	MDR risk class
Eye drops for dry eyes	IIa	IIb
Sunscreen products	I	IIa
Nasal sprays (local effect)	I	IIa
Cranberry products to prevent or cure urinary infection	IIa or IIb	III
Throat gums	I	IIa
Ultrasound gel	I	IIa

Effect of Up-classification

New class Ir or former class I turned class IIa or higher

- Involvement of NB required
- Devices that need CE-certificate for the first time are required to have it on May 26, 2020
- Shortage of NBs expected

Classification to higher risk class

- Up-classified devices may be subject to different type of conformity assessment procedure
- Higher requirements may apply to clinical evaluation
- Clinical trials may become necessary

Economic Actors

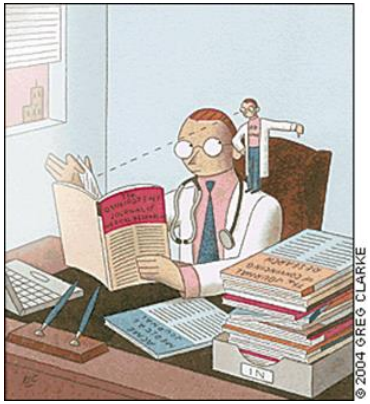
- Distributor
- Importer
  - Must register with EUDAMED
  - Ensure device CE marked and EU DoC drawn up
  - Ensure parties before it properly registered
  - Ensure device remains in compliance while in possession

- Authorized Representative (Arts. 11-12)
  - Must carry liability insurance for the devices it “represents” in the EU (Art. 9.4)
- Manufacturer (Art. 10)
  - Generally the same obligations, but more prescriptive: Make sure that you and your vendors comply with the new specifics, even if you are compliant with the MDD
  - Must carry adequate liability insurance (Art. 8.13)
- Person Responsible for Regulatory Compliance (Art. 15)
  - Person within the organization who possesses requisite experience in the field of medical devices
  - Responsible for regulatory compliance, keeping tech doc up to date, etc.
  - May be a consultant

Manufacturer's Legal Obligations

- Ensure devices designed and manufactured according to regulatory requirements;
- Establish, document, implement and maintain system for quality, risk management, post-market surveillance, vigilance;
- Conduct a clinical evaluation, including a post-market clinical follow-up;
- Draw up and keep up to date technical documentation of the devices that shows the conformity of the devices to the regulatory requirements;
- Draw up an EU Declaration of Conformity;
- Comply with UDI system requirements;
- Keep all technical documentation and Declarations of Conformity available for Competent Authorities for 10 years after last device covered by documentation placed on the market (15 years for implantables) in an official Union language;
- Ensure that procedures are in place to keep production in conformity with the regulatory requirements, including changes in regulations and standards;
- Label according to regulatory requirements (Section 23 of Annex I);
- Take necessary corrective actions to remove their nonconforming devices off the market;
- Have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.

Clinical Evaluations



Clinical Evaluation is the critical assessment and analysis of clinical data pertaining to a medical device in order to verify the clinical safety and performance of the device.

- Ongoing process throughout the lifecycle of the device
- How the manufacturer shows the device achieves its intended performance and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of the intended performance.

Notified bodies follow MEDDEV 2.7/1 Rev. 4 closely for devices currently on the market. This MEDDEV is seen as a bridge for current devices to comply with the MDR's clinical evaluation requirements

Clinical Evaluations

Clinical Evaluation Requirements

1. **Plan** (use MEDDEV to help determine what the plan should be)
2. Conduct the evaluation according to the plan
3. **Report** (use MEDDEV to help write the plan)

Question: Do you need to run a clinical investigation to answer an open question from your clinical evaluation? Your clinical evaluation should be able to (honestly) answer this question.

New/Novel Class III/Implantable device? Clinical investigation may be required!

See: MDR Arts. 61, Annex XIV

"Human clinical trials start in six months. Sooner if we run out of mice."