From a medical device idea to market

PRO-LIANCE
GLOBAL SOLUTIONS
PARTNERS IN EXCELLENCE

the regulatory perspective

Florian Tolkmitt

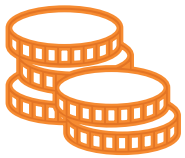
Agenda

- European Medical Technology Industry
- EU Regulatory framework
  - MDR/IVDR
  - MDCG
- 10 Key Elements
- Conclusions

European Medical Technology Industry

27.3%
of the world market

€150 billion market



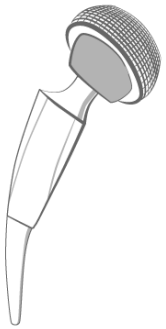
2nd
largest market

>15,300 patents

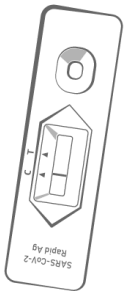
Source: The European Medical Technology Industry in figures 2022

Medical Technologies

- Medical devices



- In vitro diagnostics medical devices



- Digital health, including AI

Definition: Medical Device

‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

— devices for the control or support of conception;

— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

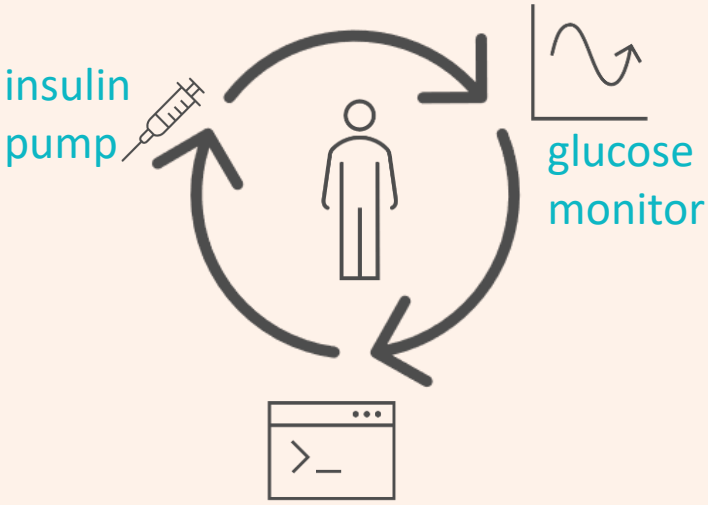
intended/medical purpose

exclusions -> medicine/food regulations

Article 2(1) of Regulation (EU) 2017/745 – MDR

Medical Devices

pacemakers



The history

2008

Consultation on medical device framework

2012

Proposal for MDR

2014

Parliament position on MDR

2015

Council position on proposal

Trilogue: Commision, Parliament, Council

2017

MDR published

2020

Planned Date of Application

The history – part II

2021

Postponed Date of Application

2024

Planned End of Transition Period

2026

Postponed End of Transition for Custom Made Class III Implants

2027

Postponed End of Transition for Class III and IIb Implants

2028

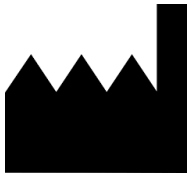
Postponed End of Transition for class IIb, IIa, Is, Im, Ir

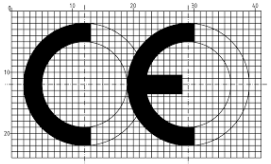
Up to 2029

Postponed End of Transition for products without medical intended purpose

European Concept of CE marking

Manufacturer Responsibility





Conformity Assessment

Notified Body involvement

Lifecycle „Approval“

“MDR”

3x more text

- Regulation (EU) 2017/745

- In comparison with the previous legislative framework

MDR facts

10 Key Elements

- EUDAMED database/transparency
- Clinical Evaluation & Investigation
- Responsibilities
- Classification
- Labeling
- Notified Bodies
- Scrutiny-Procedure
- Technical Documentation
- Post-market surveillance
- Transition timelines

The EUDAMED-Database

- Communication Interface
  - Registration
  - Clinical Investigation
  - Periodic Safety Update Reports
  - UDI
  - Trend Reporting
  - Vigilance

1 central database

The backbone of MDR

The Clinical Data

- Clinical Data from **Clinical Investigations** and/or Scientific Literature
- Must be of sufficient quantity and quality
- Zusammenfassung im Clinical Evaluation Report

$$1 > \frac{Benefit}{Risk}$$

The “Responsible”

1 responsible

- Person Responsible for Regulatory Compliance (PRRC)
  - Small companies: should have PRRC available
  - Big companies: must have an internal PRRC

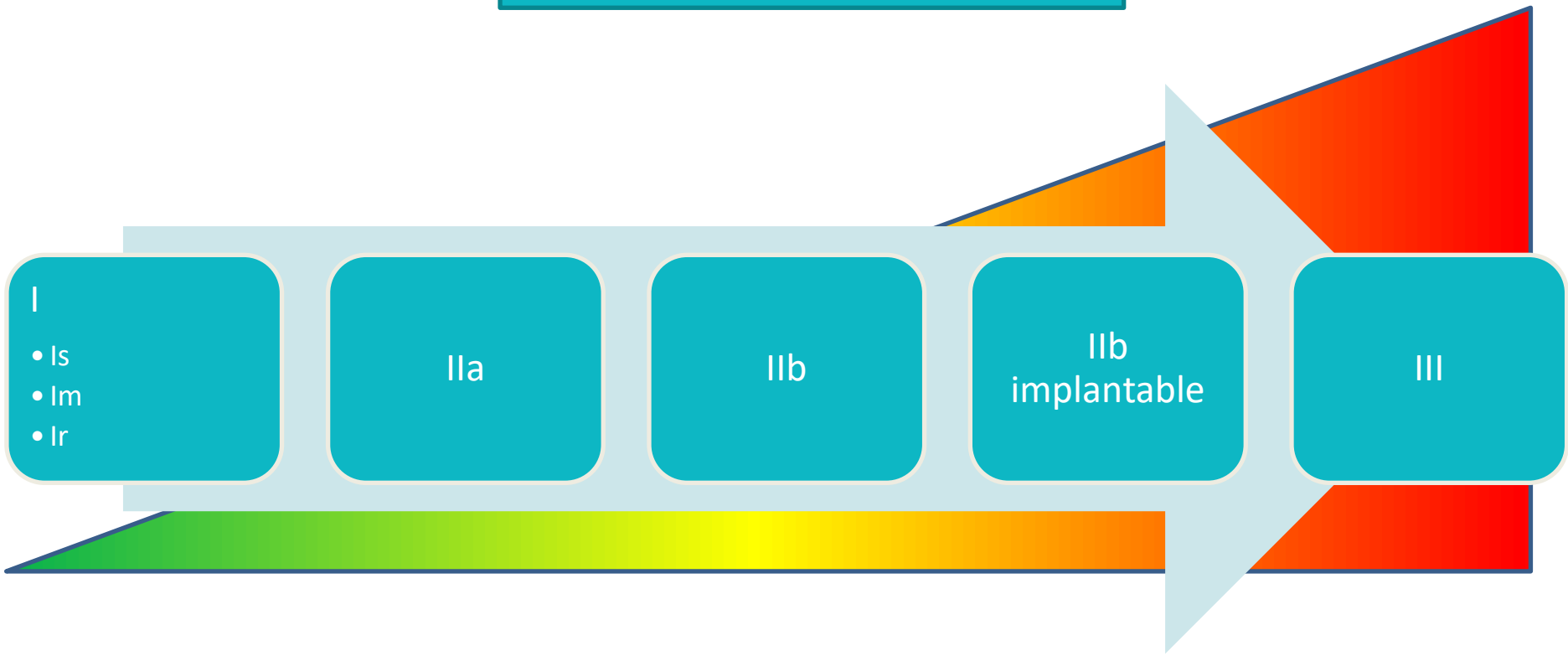
- Responsibility may be split between different people

+n responsibles

Responsibility brings Liability

The Classification

22 Rules



The Labeling & grouping

UDI

- Categorization of products
- Traceability

- UDI Elements
  - Basic UDI
  - UDI-DI
  - UDI-PI
  - fake-UDI

Notified Bodies

- Notified Bodies for MDR are listed on the NANDO Website 

39 NBs for MDR

Source: https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies/notified-body-list?filter=bodyTypeId:3,legislationId:34

Scrutiny Procedure

after Clinical Evaluation Consultation

10 Opinions

- **Orthopaedics, traumatology, rehabilitation, rheumatology**
- **Circulatory system**
- **Neurology**
- **General and plastic surgery and dentistry**

All Applications for Consultation → May be scrutinized by European Commission

Source: https://health.ec.europa.eu/medical-devices-expert-panels/experts/list-opinions-provided-under-cecp_en

The Technical Documentation

- Description/Specification
- Manufacturing information
- General Safety and Performance Requirements (GSPR)
- Benefit-Risk-Analysis and Riskmanagement
- ***Verification and Validation***

2

Technical Documentations

- Information from the Post-Market Phase

Post-Market Surveillance

- Continious Updates over the lifecycle & lifetime

Lifecycle „Approval“

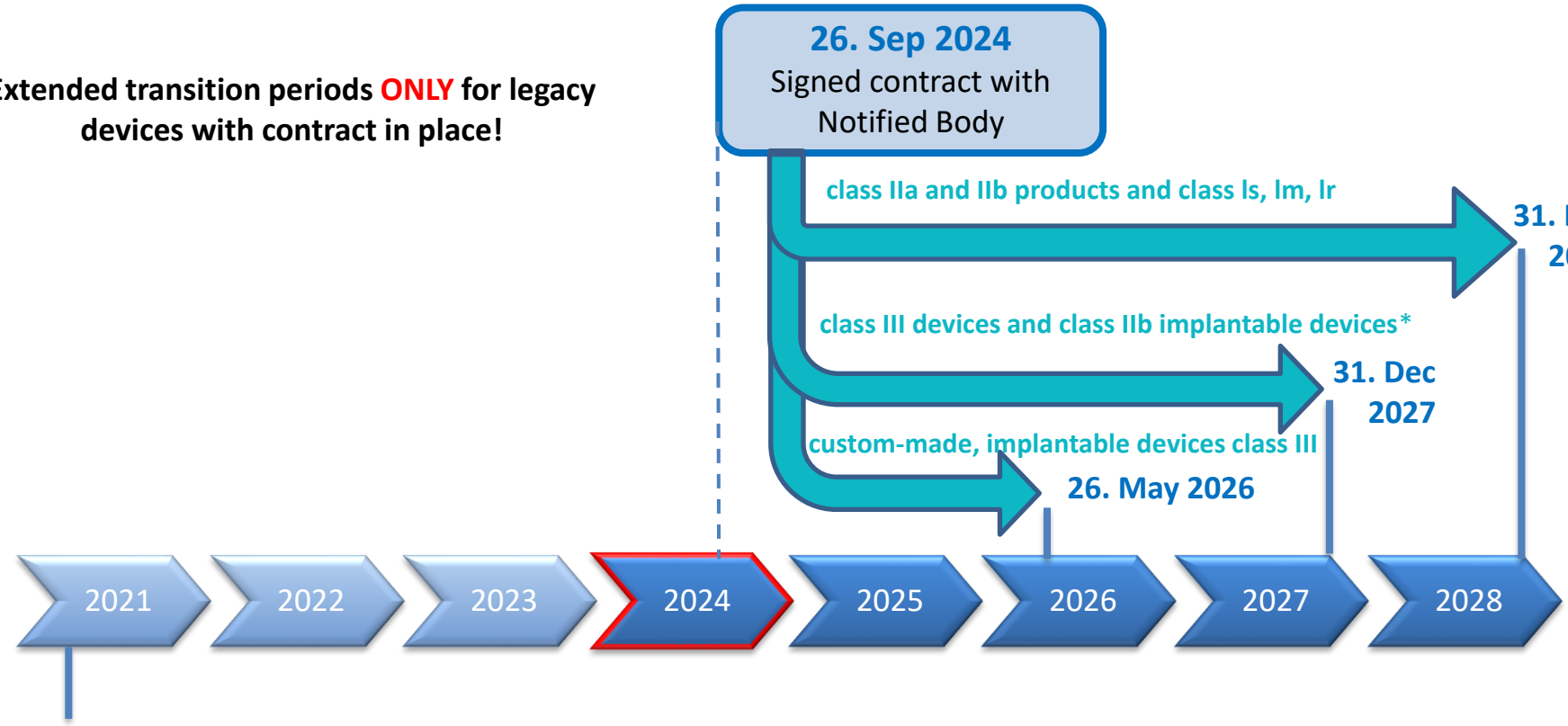
PSUR update depending on risk class

1 time per year or

every 2nd year

Transition Timelines
Article 120 MDR

Extended transition periods ONLY for legacy devices with contract in place!



26. May 2021
Date of Application

*except sutures, staples, dental fillings, braces, dental crowns, screws, wedges, plates, wires, pins, clips and connectors

For all new devices MDR applies **immediately**

Take Home Messages

MDR might be confusing

Compliance is hard work

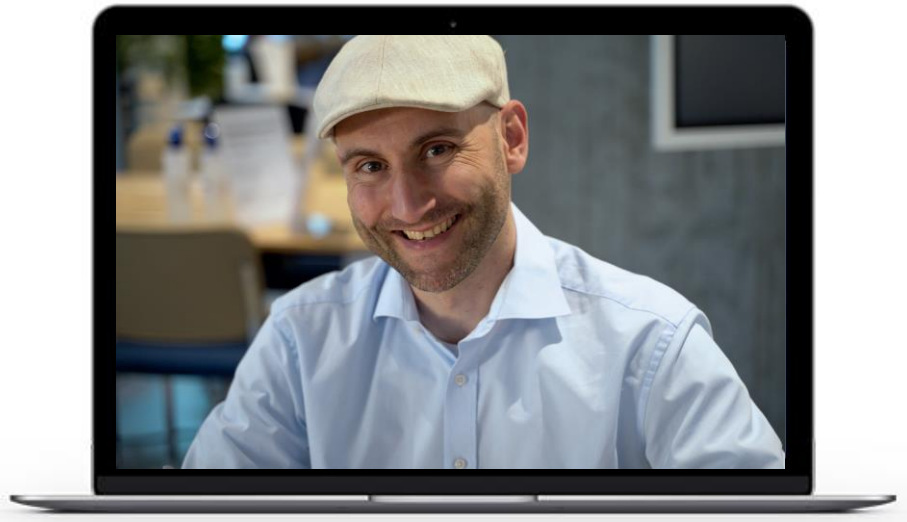
Non-compliance is punishable by law

Start early!

Communicate with Notified Bodies

Work on Clinical Data

PRO-LIANCE
GLOBAL SOLUTIONS
PARTNERS IN EXCELLENCE



Florian Tolkmitt
PRO-LIANCE FOUNDER, REGULATORY & CLINICAL EVAL. EXPERT

Florian Tolkmitt is one of the founders and managing directors of PRO-LIANCE. Within the team he is responsible for Clinical Evaluation, Technical File and Risk Management. As a creative mind, he is always setting new impulses in the company and therefore ensures the continuous development of all employees. With the needs of the customer in focus, he is always looking for new solutions.

ft@pro-liance.com
https://www.linkedin.com/in/floriantolkmitt/
https://pro-liance.com/