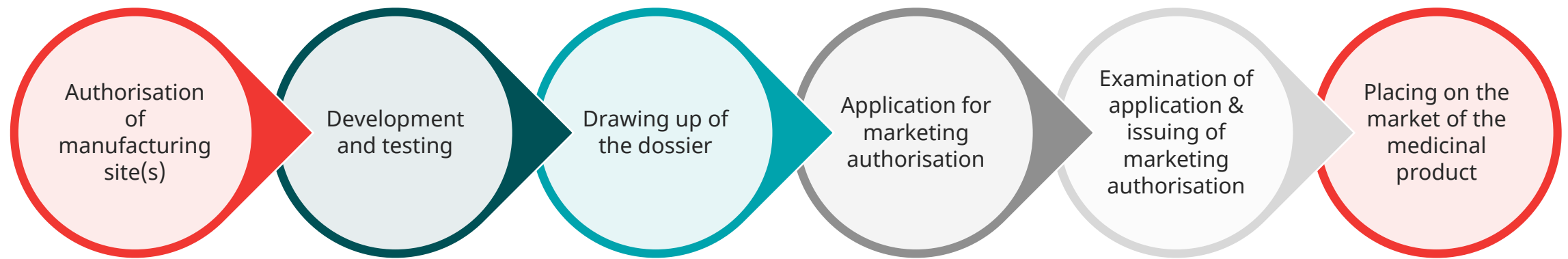


● The Notified Bodies perspective – opportunity to collaborate with medicine regulators for qualification of novel methodologies?

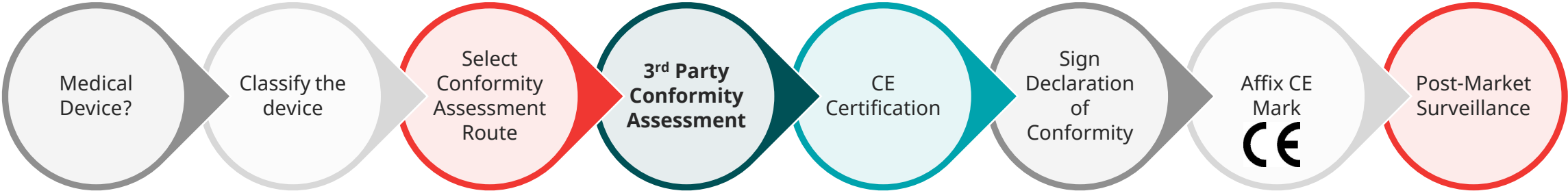
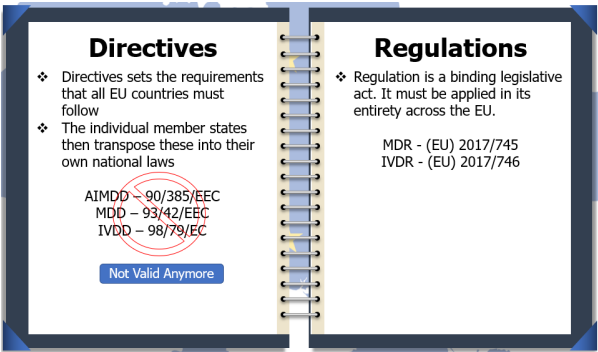
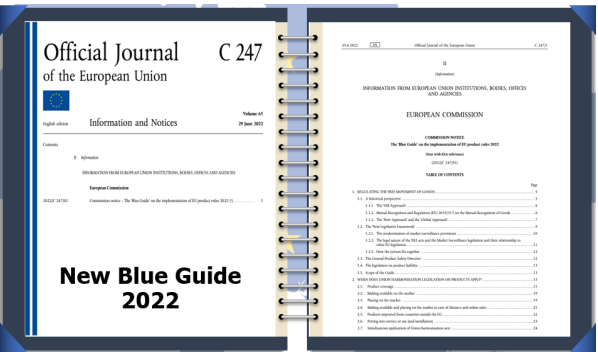
Daniela Seneca
Regulatory Lead Artificial Intelligence, BSI Group

17 April 2023





Medical Device Conformity Assessment – New Legislative Framework



Key Concepts of the New Approach Legislation

Classification of devices by risk

Conformity assessment

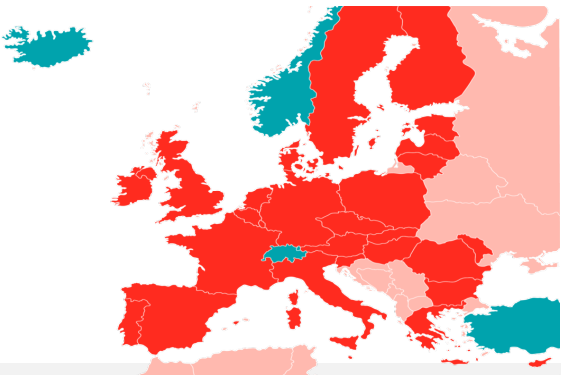
- ❖ Graduated to risk
- ❖ Carried out by Notified Body or manufacturer

General safety and performance Requirements stated in a general way

- ❖ Details in harmonized standards

Manufacturer holds technical documentation, leading to:

- ❖ Written Declaration of Conformity
- ❖ CE marking



Medical device definition in Regulation EU 2017/745

4

‘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 specific medical purposes** of:

- **diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,**
- diagnosis, monitoring, treatment, alleviation of or compensation for 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:

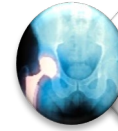
- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices



Devices incorporating tissues or cells of Human origin (non-viable)



Article 117 Drug/Device combinations



Custom-made Class III implants



Devices without a medical purpose – Annex XVI

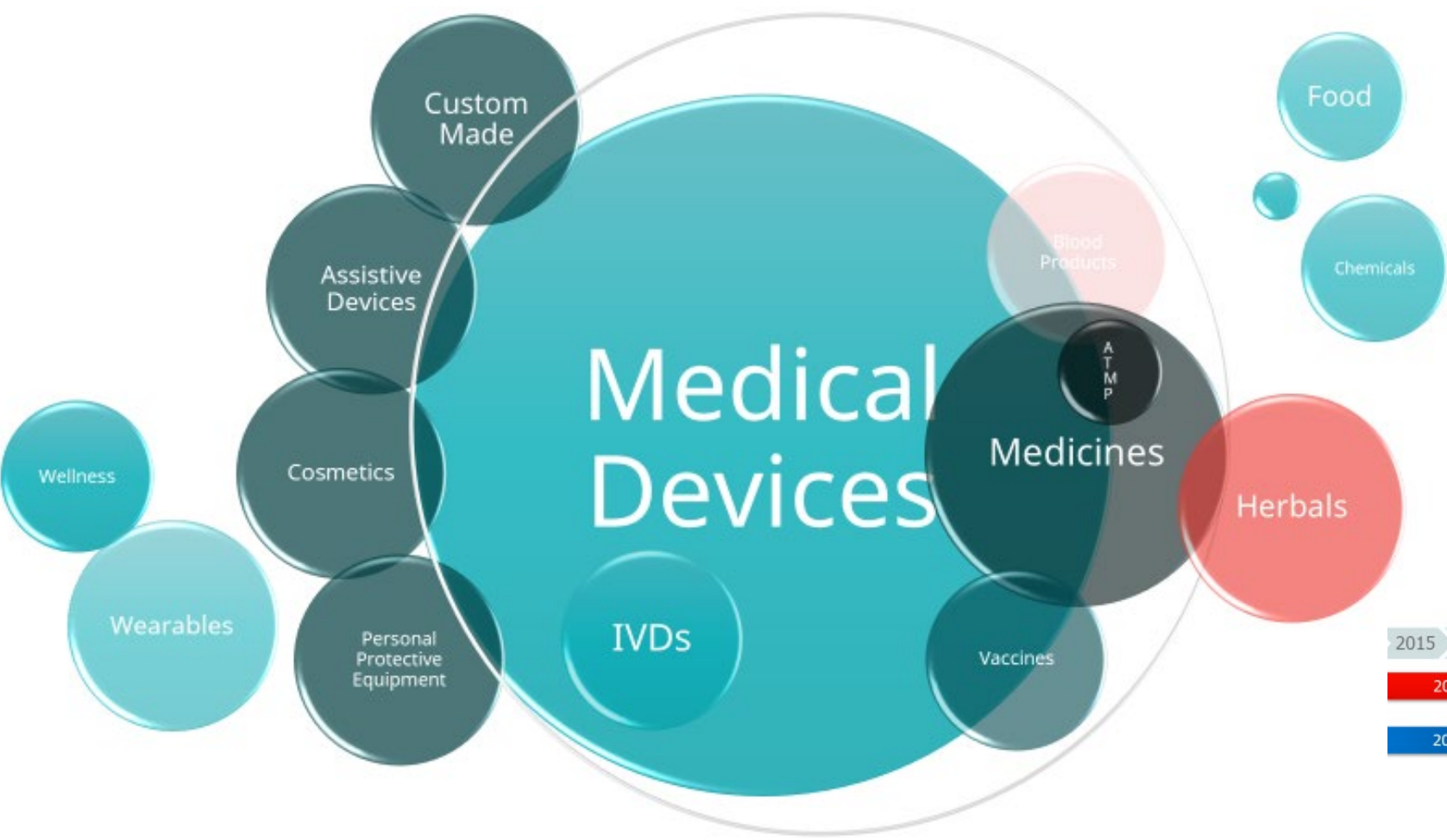


Class I re-usable surgical instruments



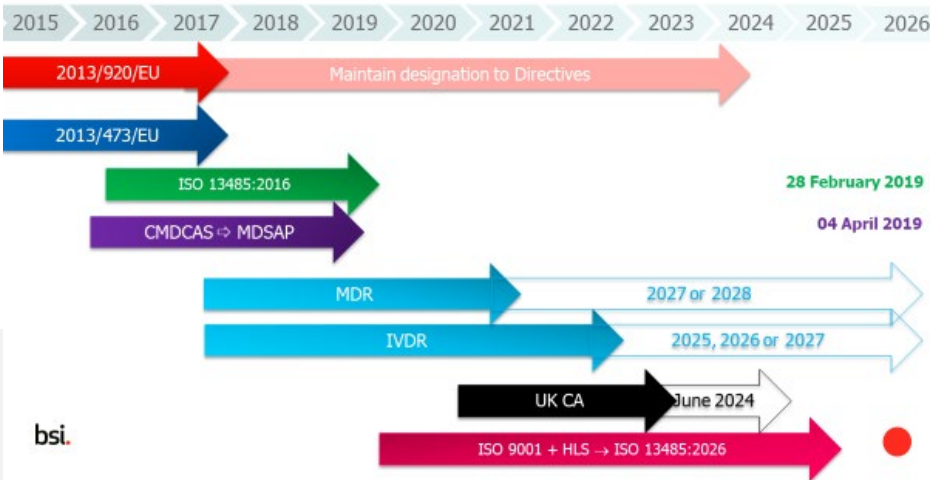
Software that was Class I under MDD and now up-classified

Health technologies – wide knowledge and resilience to changes

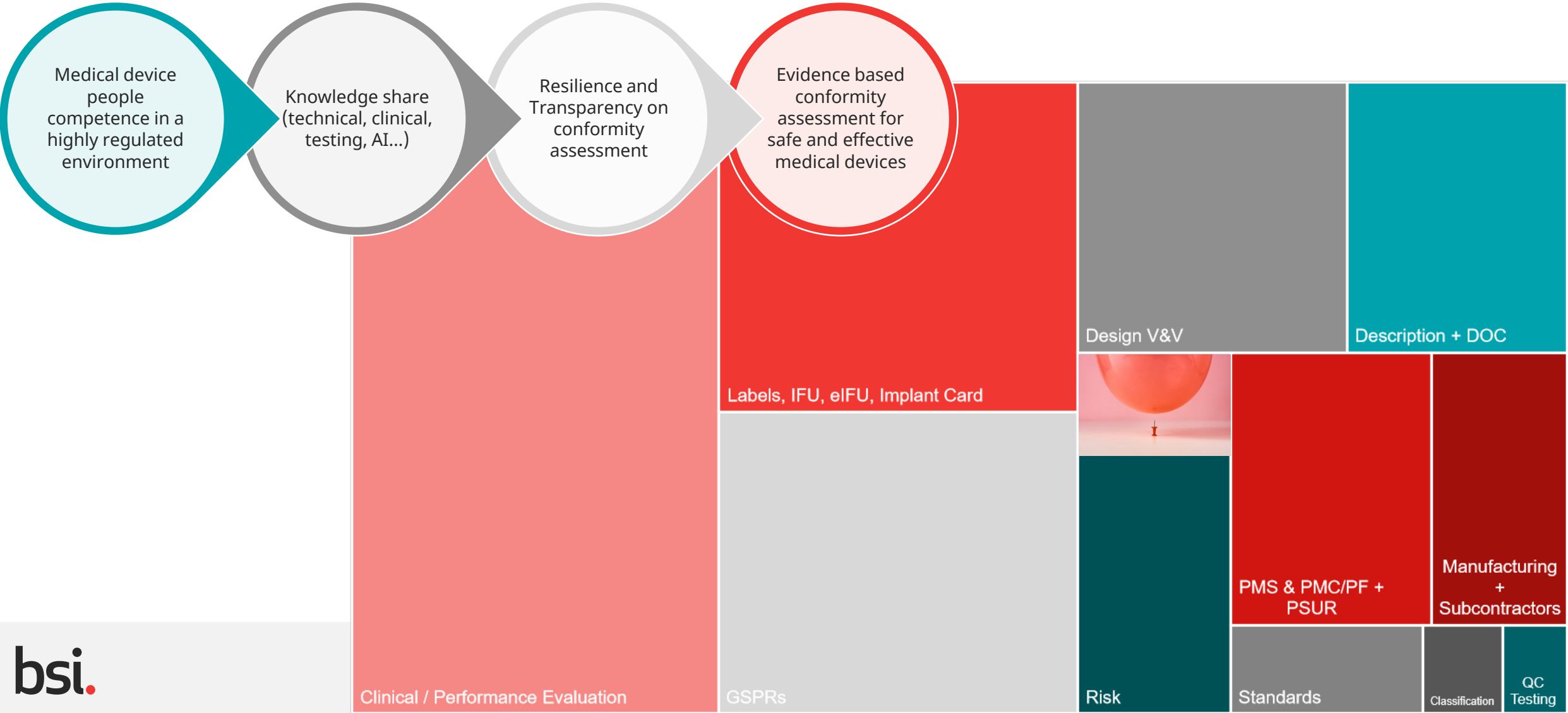


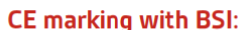
Brussels, 21.4.2021
COM(2021) 206 final
2021/0106(COD)

Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS



Shared objectives and possible collaboration on novel methodologies





This guide to our certification process will take you from your application to BSI through to a CE mark certificate being issued to your company.

Manufacturer applies to RFI

Following an initial discussion with our local commercial team, you will need to submit a Company Information Form; this gives BSI the information we need about your company and products in order to provide an accurate proposal. Your application should include the information detailed in the appropriate Annex of the Medical Devices Regulation (MDR) or IVD Regulation (IVDR), based on your chosen conformity assessment route: • Annex IX section 2.1 • Annex X section 2 (MDR) • Annex XI section 6.1 (MDR) or Annex XI section 3.1 (IVDR)

the Company Information Form. Once agreement between your organization and the designated team, including the Technical Manager to oversee certification activities, will remain your point of contact for all

contract for completeness, requesting
appropriately qualified Assessors to

signed to assess your system to
ssment: Stage 1 will review the
nplementation of your QMS and its

ent Microbiologists will be required.

be assigned to conduct your Product
ation and the appropriate conformity
iteness and content of your
that provide evidence of conformity to
re identified. Your product(s) may be
ation with a Competent Authority or the

... to the applicable requirements,
undertaken and, if satisfied that the
... They will then submit the information

onsisting of a Technical and Regulatory
is allows verification of, and
ows are conducted by BSI staff with the

ur organization

king excellence a habit

bsi.

...making excellence a habit.™

Author - Dr. Amie Smirthwaite, Global VP for Clinical Services, RMO+



MDR Documentation Submissions

Best Practices Guidelines

bsi.

...making e

MDR Conformity Assessment Routes

Contents

- Class Is/Im/Ir devices
- Class Ila devices
- Class Iib Annex VIII rule 12 devices
- Class Iib Implantable – Well Established Technologies (WET)
- Class Iib non-implantable non rule 12 devices (non WET)
- Class Iib Implantable devices (excluding WET)
- Class III non-implantable devices
- Class III Implantable devices
- Custom-made Class III Implantable devices
- Custom-made devices (excluding custom-made Class III implantable devices)
- Class I devices (excluding Class Is/Im/Ir devices)

DISCLAIMERS:
Information presented in the conformity assessment flow charts and tables below is based on our current understanding of the MDR requirements at the time of publishing this document; subject to change.

The tables do not cover assessments under the conformity routes Annex X (Type Examination) and Annex XI Part B (Product Verification) which may require additional tests or examinations of the devices. The tables present a generalization of the requirements based on the classification of devices and some exceptions may apply.

bsi

...making excellence a habit.



Person responsible for regulatory compliance (PRRC) - MDR/IVDR Article 15

With the MDR and IVDR, European regulators aim to ensure companies have a regulatory expert – a Person Responsible for Regulatory Compliance (PRRC) – at their disposal, to ensure that the company is meeting certain specific EU requirements.



Software as a medical device - A comparison of the EU's approach with the US's approach

The International Medical Device Regulators Forum (IMDRF) aims to accelerate international medical device regulatory convergence. Through the IMDRF, regulators reached consensus on what software is considered a medical device. Regulators call it 'software as a medical device' (SaMD). This paper provides a comparison of how SaMD is regulated in the US and in the EU.



Machine learning AI in medical devices

How is AI different from traditional medical devices and medical software and what are the implications of those differences? What controls are necessary to ensure AI in healthcare is safe and effective?



Medical device clinical investigations – What's new under the MDR?

The conduct of a clinical investigation is one of the most time consuming and resource intensive activities that a medical device manufacturer can face. This paper discusses important new requirements for pre-market and post-market clinical investigations under the European MDR.



bsi.

<https://www.bsigroup.com/en-GB/medical-devices/resources/whitepapers/>