BSI Insight Series

Webinar #2

Cracking the Code: *MDR, IVDR and UKCA Classification and Indications for Use*

December 9, 2025

SMEs and Startups are vital drivers of healthcare innovation, representing approximately **95% of medical device manufacturers in Europe**[1]. Yet, the complexity of EU regulations - combined with limited internal resources - can make compliance for startups a significant challenge.

We are here today, collectively, because startups play a critical role in addressing unmet clinical needs and advancing technological innovation. Since 2007,**EU-funded Startups have raised over €70 billion** in venture capital and generated more than **€500 billion in enterprise value**[2]**.**

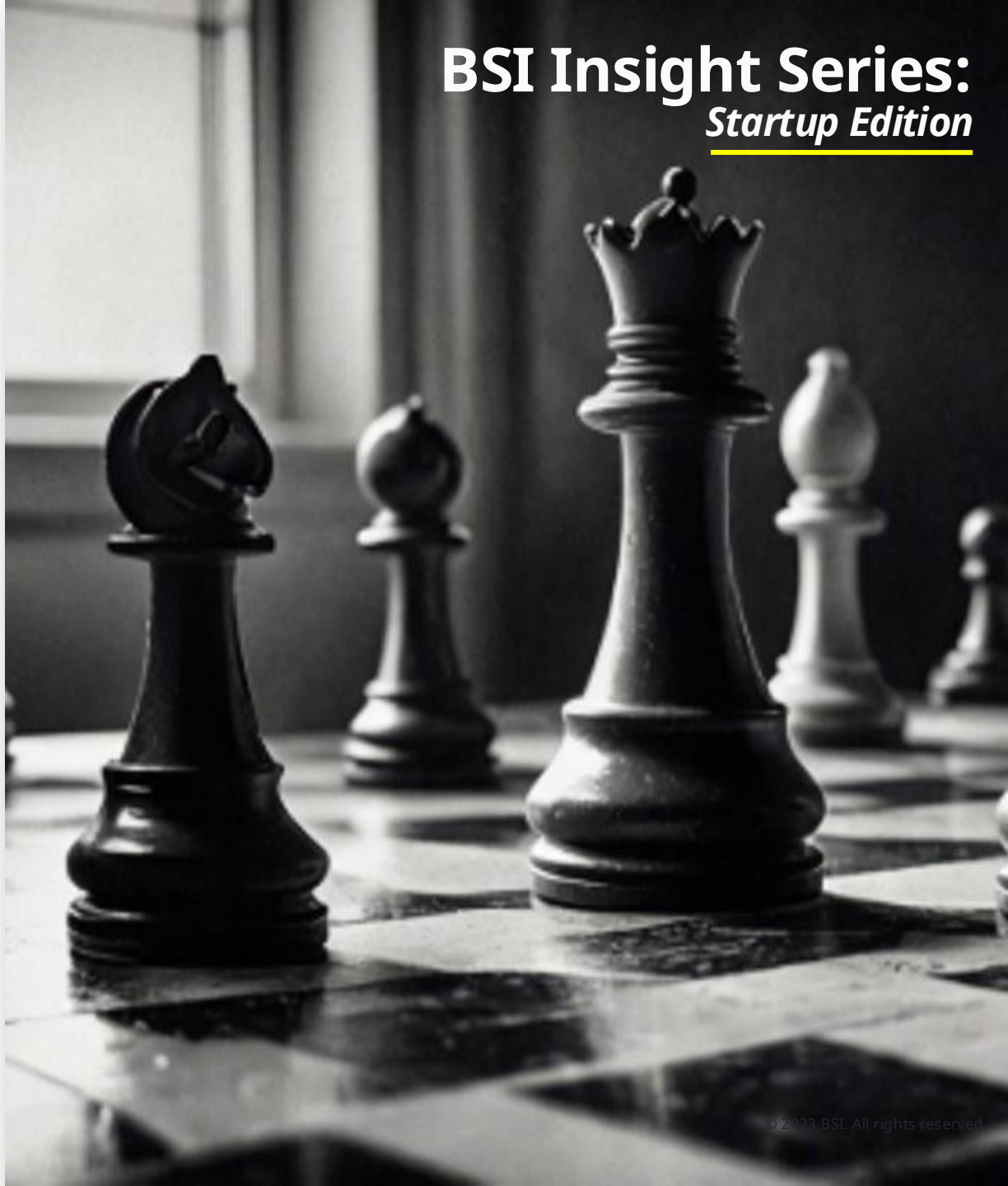
1 MedTech Europe. (2022). The European medical technology industry in figures 2022.
2 European Commission. (2025). The EU startup and scaleup strategy: Choose Europe to start and scale.

With us today...

Kevin Madden
Head of Professional Development

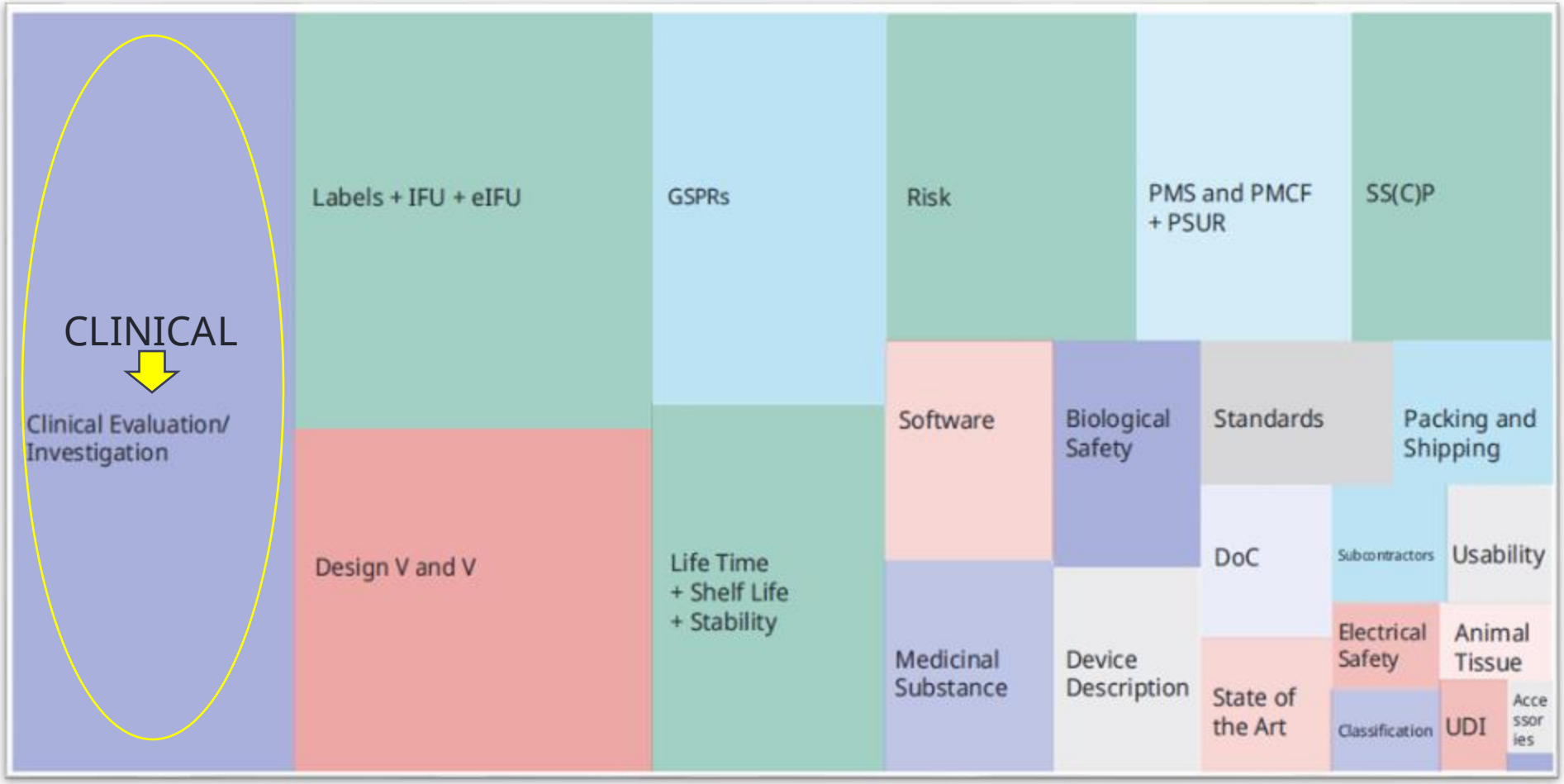
Richard Holborow
Head of Clinical Compliance

Jonathan Page
Technical Training Team Manager



Key Focus Areas for Startup Success - Clinical

Number of Non-conformities raised during technical documentation review:
Key Message – More Non-Conformities in the Clinical Evaluation Areas



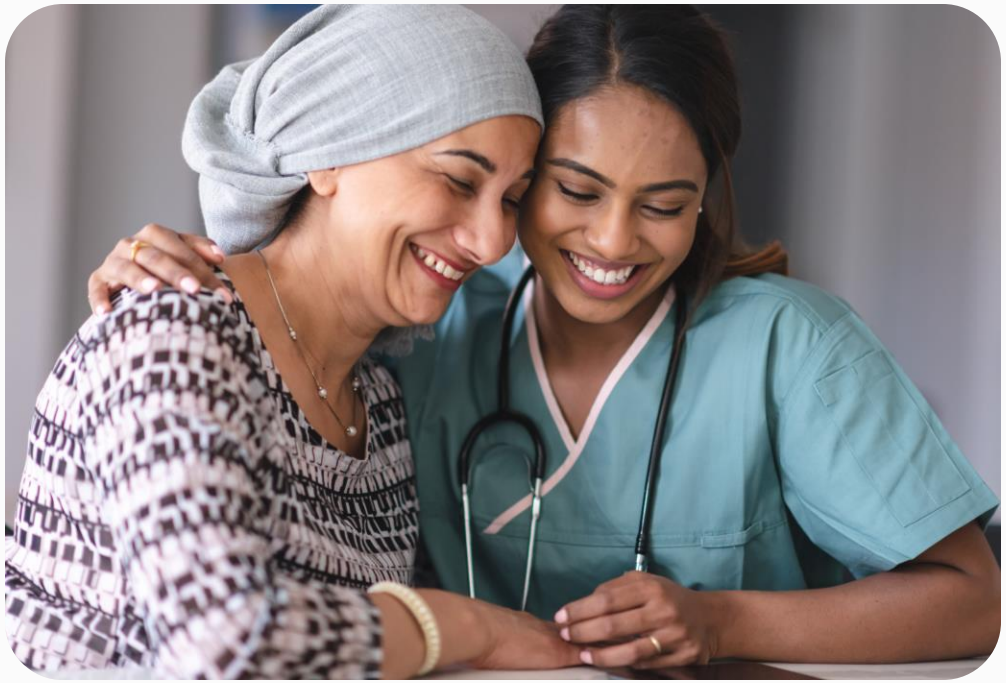
Define your Intended Purpose & Clinical Benefit

- What is the **#1 Reason for Refusal - Clinical Evaluation of a Regulatory Submission:** A clear intended purpose is a cornerstone to regulatory submission & success to market your device. The **first step** in your clinical evaluation and regulatory journey is to define your **intended purpose.**

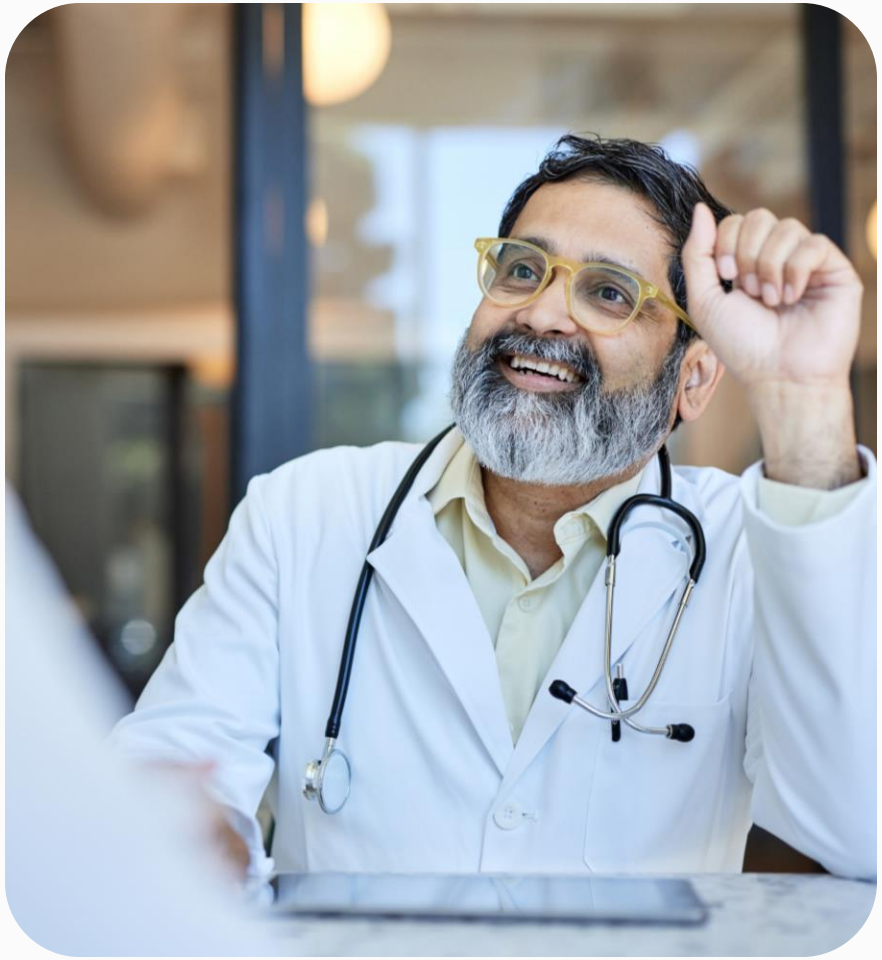
- *The intended purpose means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation; (MDR Article 2 (12))*

- **Clinical benefit** is critical to understanding what you will be measuring as a positive impact of your device.

- *'clinical benefit' means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health;* (MDR Article 2 (53))



Define your Intended Purpose & Clinical Benefit



<u>The following information should be considered within the *Intended Purpose* of the device:</u>

- ✓ Name of disease or condition/ clinical form, stage, severity/ symptoms or aspects to be treated, managed or diagnosed
- ✓ Patient populations (adults / children / infants, other aspects)
- ✓ *Intended user (use by health care professional / lay person)*
- ✓ Organs / parts of the body / tissues or body fluids contacted by the device
- ✓ Duration of use or contact with the body
- ✓ Repeat applications, including any restrictions as to the number or duration of reapplications
- ✓ Contact with mucosal membranes/ invasiveness/ implantation
- ✓ Contraindications
- ✓ Precautions required by the manufacturer
- ✓ Single use / reusable
- ✓ Other aspects

Meddev 2.7/1 rev 4 Section A3 Device Description

Define your Intended Purpose & Clinical Benefit

'clinical performance' means the ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer; (Article 2 (52))

'clinical benefit' means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health; (Article 2 (53))

State of the Art & Objectives

The **next step** is to consider your intended purpose and to consider similar diagnostic/treatment options that currently exist.

- This is done by looking at the ‘State of the Art’ often through a robust literature search.
- The **depth and breadth of the search will depend on your Intended Purpose**.
- The results of this search will lead you to answer this critical question…. *an indicative list and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the various indications and for the intended purpose or purposes of the device; (Annex XIV Part A (1) (a))*
- In other words: *What objective criteria can be determined that my device is better than or equal to what is currently available?*

Poll Quiz Question

Examples for intended purpose.

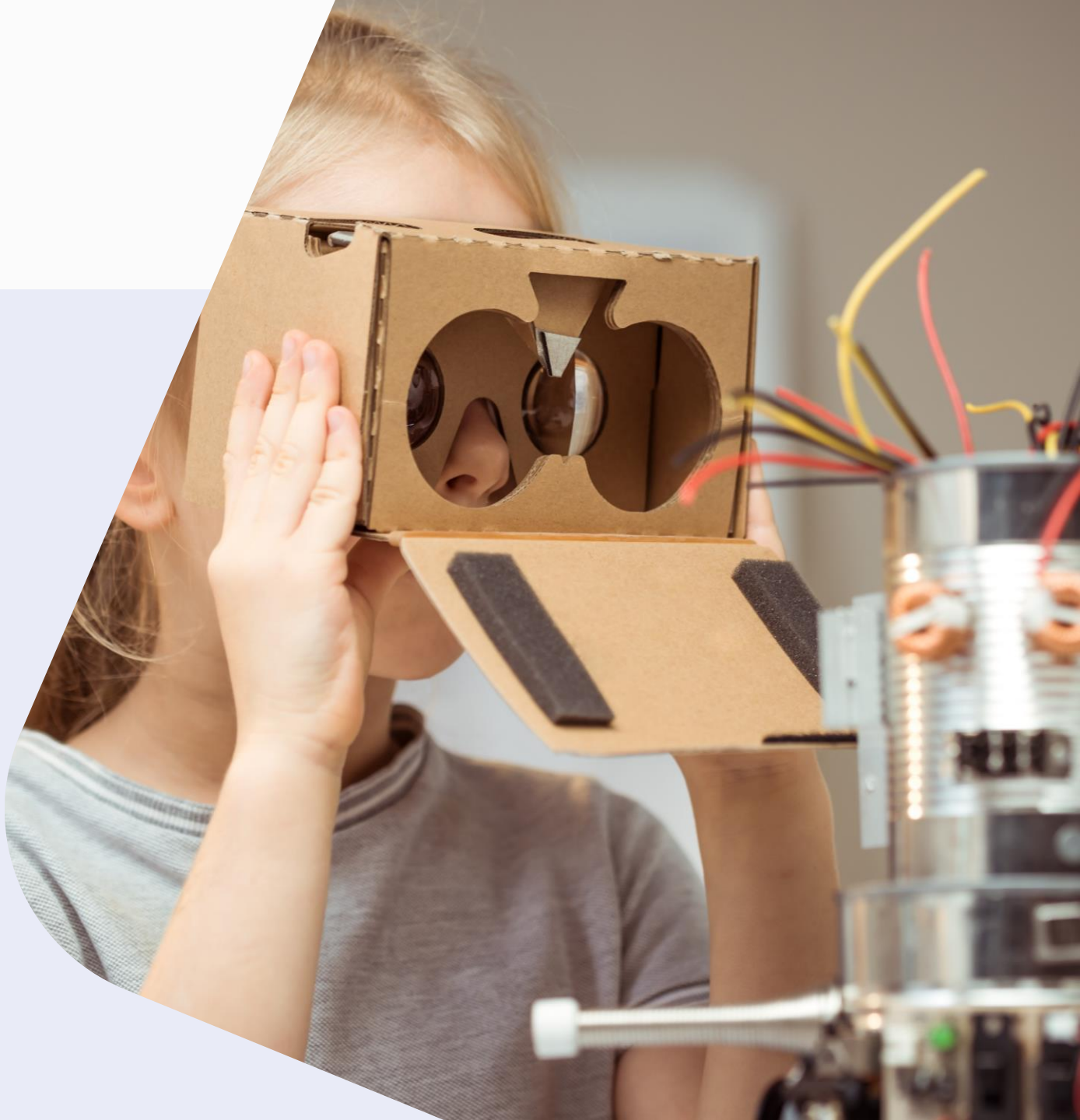
Poll 1:

What intended purpose statement would be most appropriate for a Device: Glucose Monitor

A. *"To monitor health parameters in people."*

B. *"To measure blood glucose levels in adult patients aged 35-45 with Type 1 diabetes admitted to the ICU at hospital settings only."*

C. *"To quantitatively measure blood glucose levels in individuals with diabetes for self-monitoring at home or in clinical settings."*



Poll Quiz Question

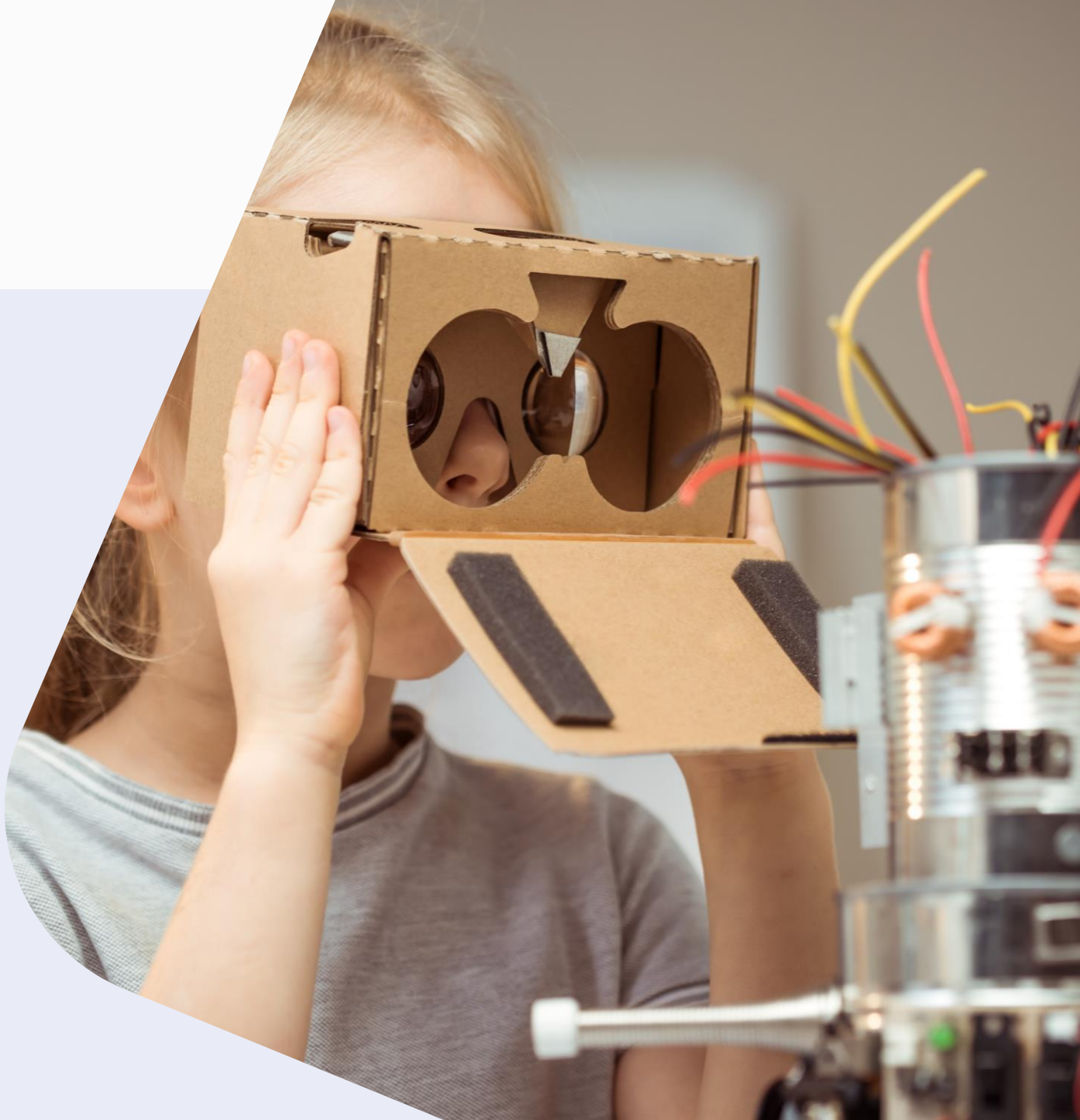
Examples for intended purpose.
Poll 2:

What intended purpose statement would be most appropriate for a MRI Analysis Software as a Medical Device (SaMD)

A. *"To analyze brain MRI images using artificial intelligence to assist healthcare professionals in detecting neurological disorders in adult patients."*

B. *"To improve patient outcomes using artificial intelligence."*

C. *"To analyze MRI scans for detection of left temporal lobe epilepsy in male patients aged 40–45 at Neurology Clinics."*

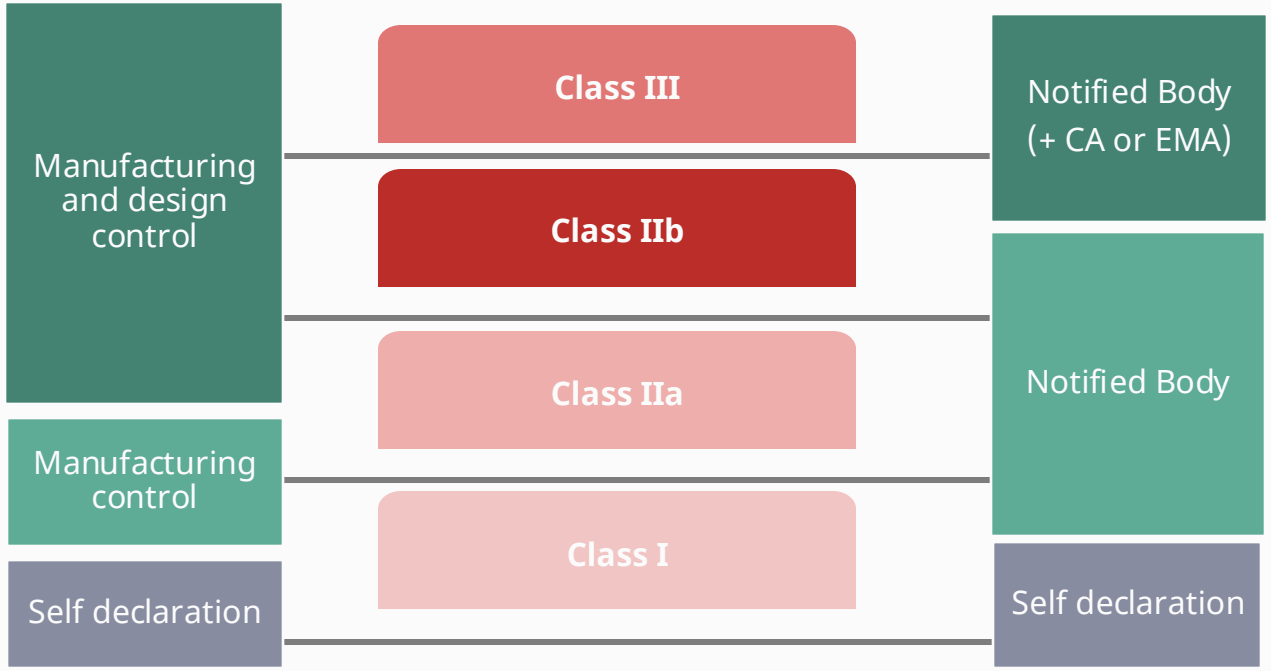


Medical Device Classification

Why do we classify?

1. Classification ensures regulatory control matched to risk
2. Proper selection of route to CE Marking
3. Manufacturer is responsible for classification

Levels of Notified Body Involvement



Annex VIII: Classification Rules (MDR / UKCA)

Transient
Continuous use for less than 60 minutes

Short Term
Continuous use for between 60 mins & 30 days

Long Term
Continuous use for more than 30 days

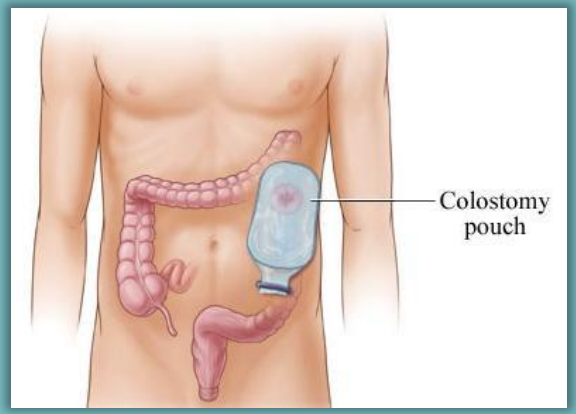
Duration of Contact: Chapter I

Annex VIII: Classification Rules (MDR / UKCA)

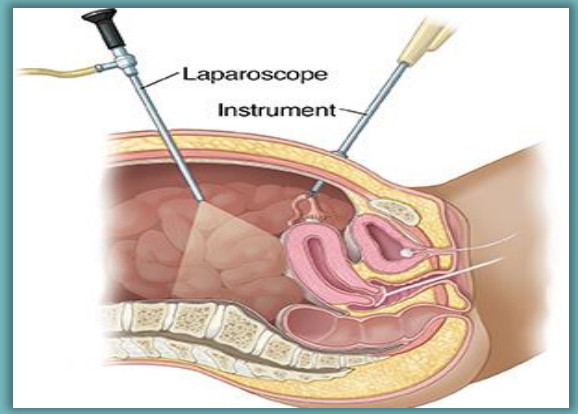
- Continuous use excludes temporary interruption of use or temporary removal for processes such as cleaning, disinfection etc
- Continuous use means accumulated use if a device is replaced immediately with another of the same type

Invasive

Penetrates inside the body via a body orifice or through the surface



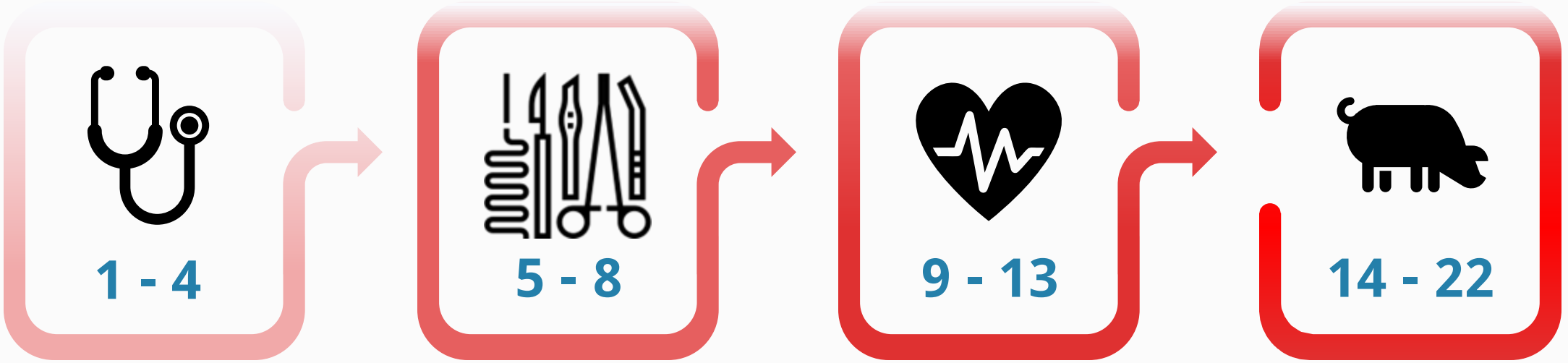
Body Orifice Invasive
Natural opening or permanent artificial opening, e.g. stoma



Surgically Invasive
Penetrating the surface in context of surgical intervention

Degree of Invasiveness: Chapter I

Annex VIII: Classification Rules



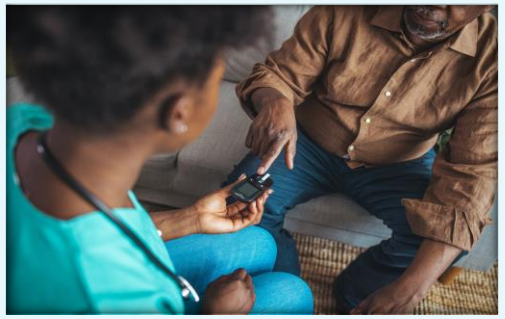
Non invasive devices **Invasive devices** **Active devices** **Special rules**

Classification Rules IVDR – Who, Where, How?

Professional versus Lay Person

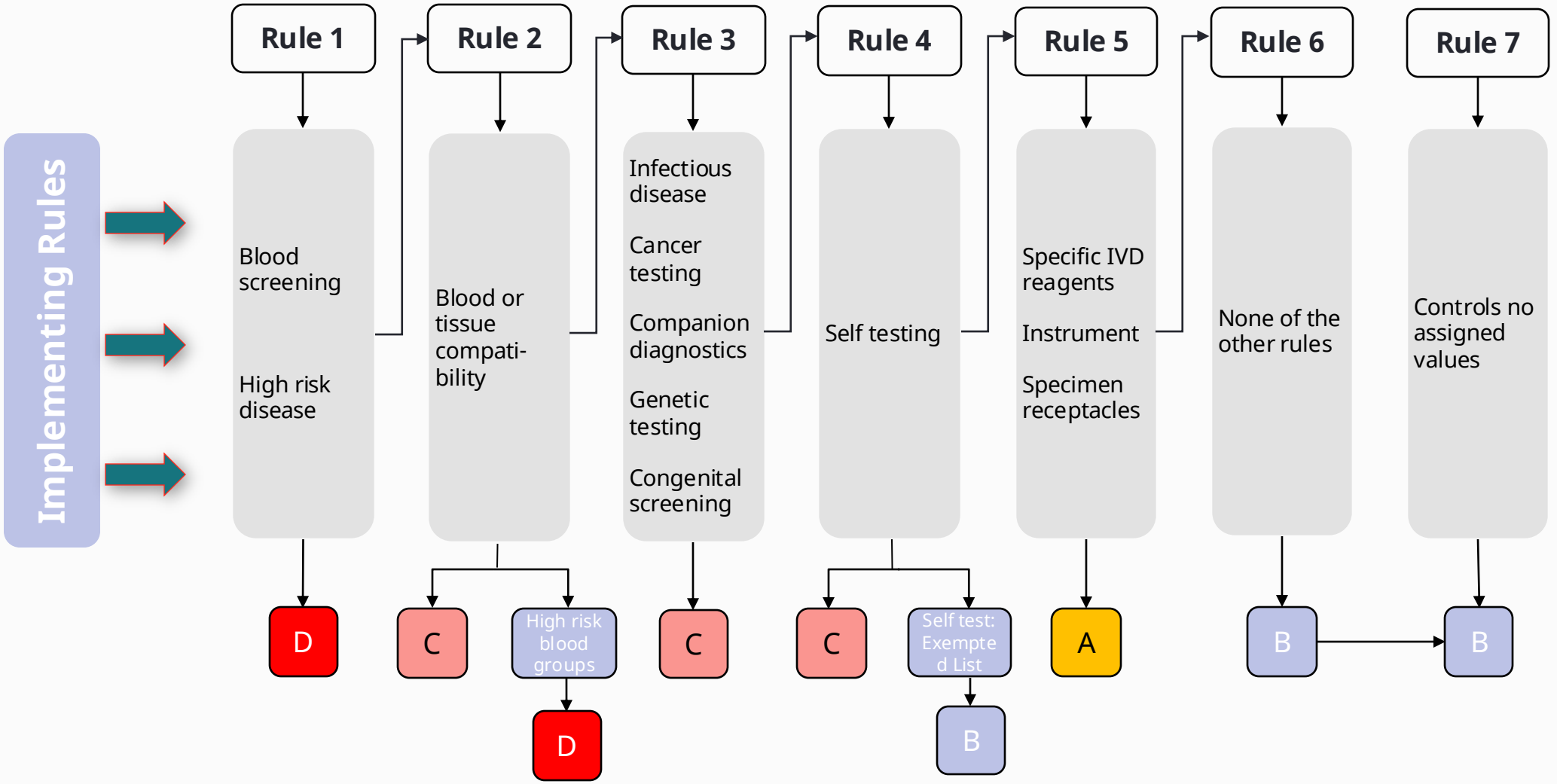
This is called “self-testing”

Near patient



- Outside a laboratory environment
- Generally near to or at the side of the patient
- By a healthcare professional

Rules for IVDR Classification



All near patient tests are classified in their own right, they can be D, C, or B, depending on intended purpose

Poll Quiz Question

Classification

Poll 3: This device is wound dressing that is intended to be used on injured or exposed skin for no more than a week, but is made with animal tissue.

A. Class IIa
B. Class IIb
C. Class III

Poll Quiz Question

Classification

Poll 4: This software is intended to diagnose cardiac events for patients that could lead to death.

A. Class III
B. Class IIb
C. Class I

Poll Quiz Question

Classification

Poll 5: This IVD device is a self test for pregnancy.

A. Class B
B. Class D
C. Class C
D. We do not have IVD in our portfolio

Poll Quiz Question

Classification

Poll 6 (Optional for time): This software is an AI tool to help doctors monitor breathing patterns for patients on ventilators.

A. Class IIa
B. Class IIb
C. Class I

Summary

05 Apply the applicable rule(s); if multiple apply, apply the highest classification

04 Consider the implementing rules

03 Consider the definitions

02 Confirm it is a medical device

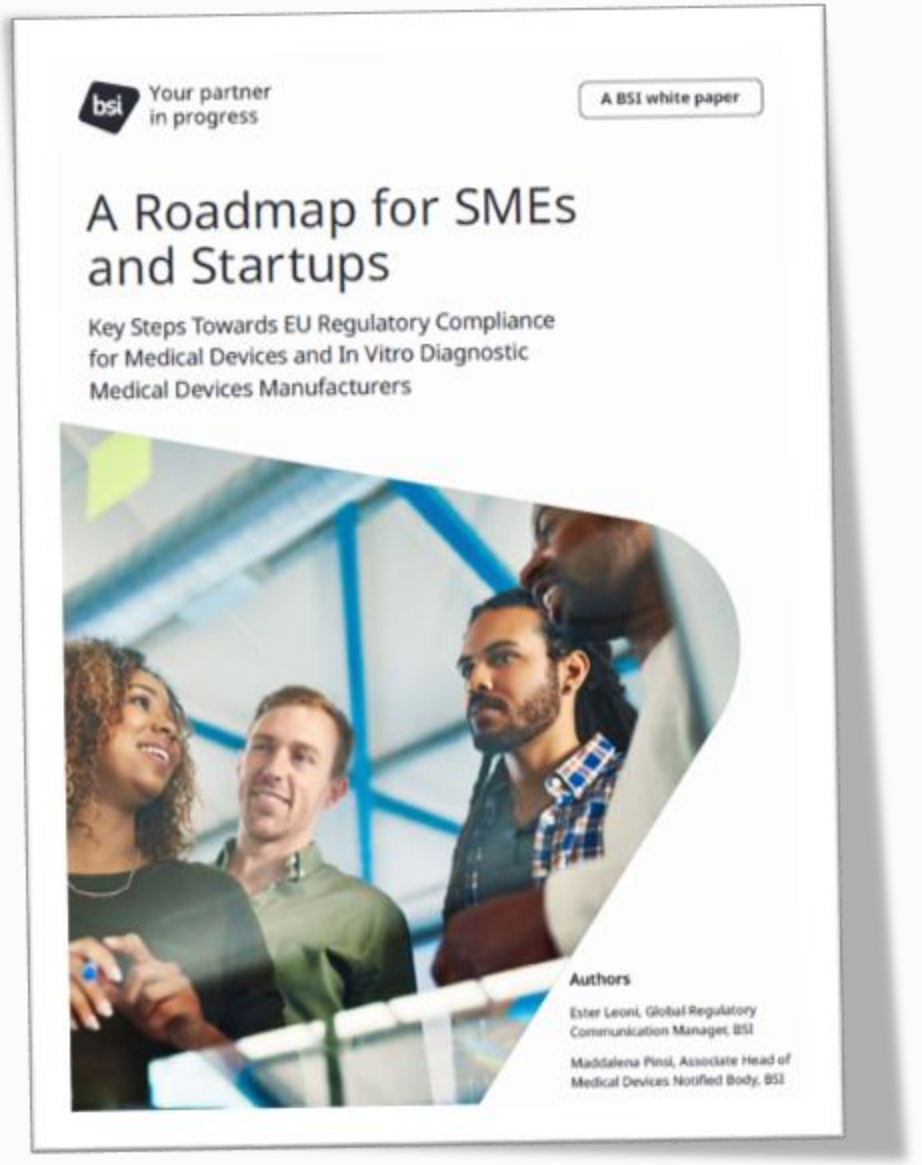
01 Intended purpose – As defined by the manufacturer (medical or not)

Questions?

Further Resources

BSI White papers - [Medical Device White Papers]

- MDR Technical documentation
- IVDR Classification White Paper
- Roadmap for Small-Medium Enterprise and Startups White Paper
- ([A Roadmap for SMEs and Startups | BSI])



BSI Insight Series:
Startup Edition

Six webinars to help you ***align*** Regulatory Strategy with Startup Growth Stages:

Webinar Series (Every 2nd Tuesday of the Month):
Nov 11: Roadmap to Market Access: Understanding Global Device Regulations

Dec 9: Cracking the Code: MDR, IVDR and UKCA Classification and Indications for Use

Jan 13: How to Use Risk Mapping to Set Up Your Project for Success

Feb 10: Demystifying Design Controls and Clinical Planning

March 10: Building Safer Devices with Human Factors and Usability Engineering

Apr 14: From Prototype to Production: Manufacturing Pathways Explained

To register for the future Insight Series webinars: click here

Thank you!

December 9, 2025