Personalised Medical Devices – What You Need To Know

An overview of the MDR requirements and practical considerations

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BSI

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AGENDA

- Definitions of personalized Medical Devices
- Legislation & Guidance
- Requirements
- Practical aspects of classifying Personalised Medical devices
- Misconceptions about classifying as custom?
- Examples

Reason for attending?

a) Interest
b) MFR certified personalised MD
c) MFR custom
d) Unsure of conformity route

Device;

- **Prescription**
- **Not standard offering**
- **Defined specification**
- **Same device regularly supplied**
- **Low volume**

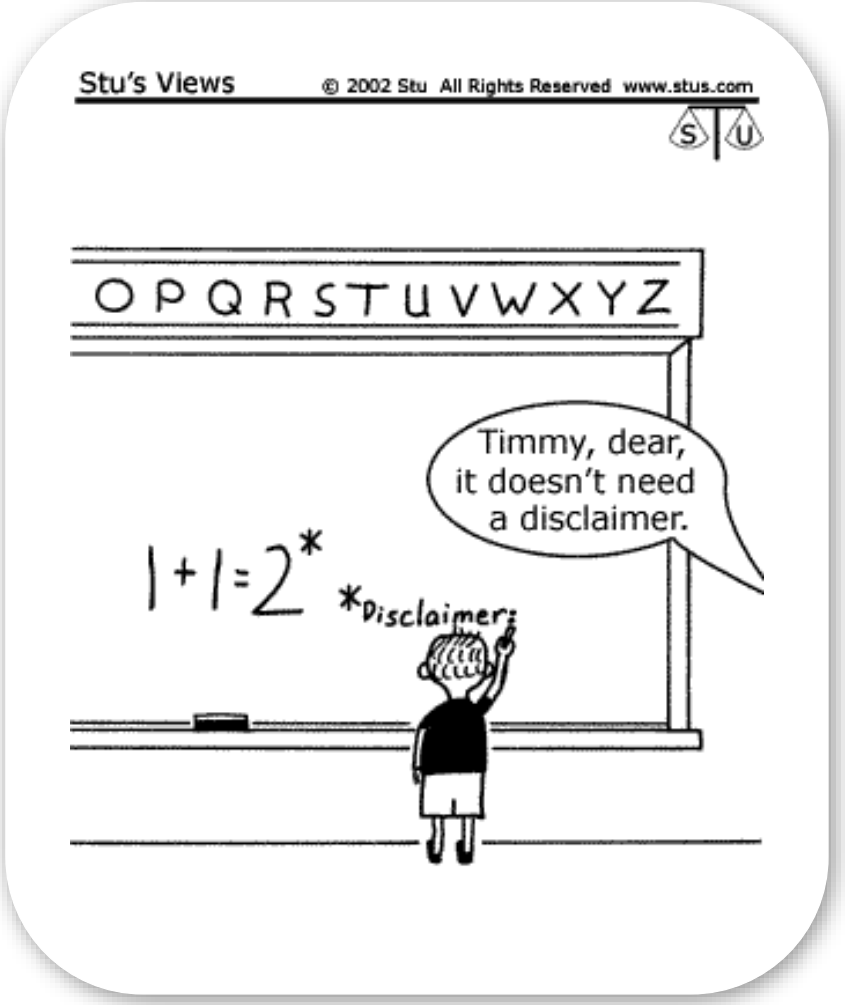
Is this a custom made device?

a. Yes
b. No

Disclaimer

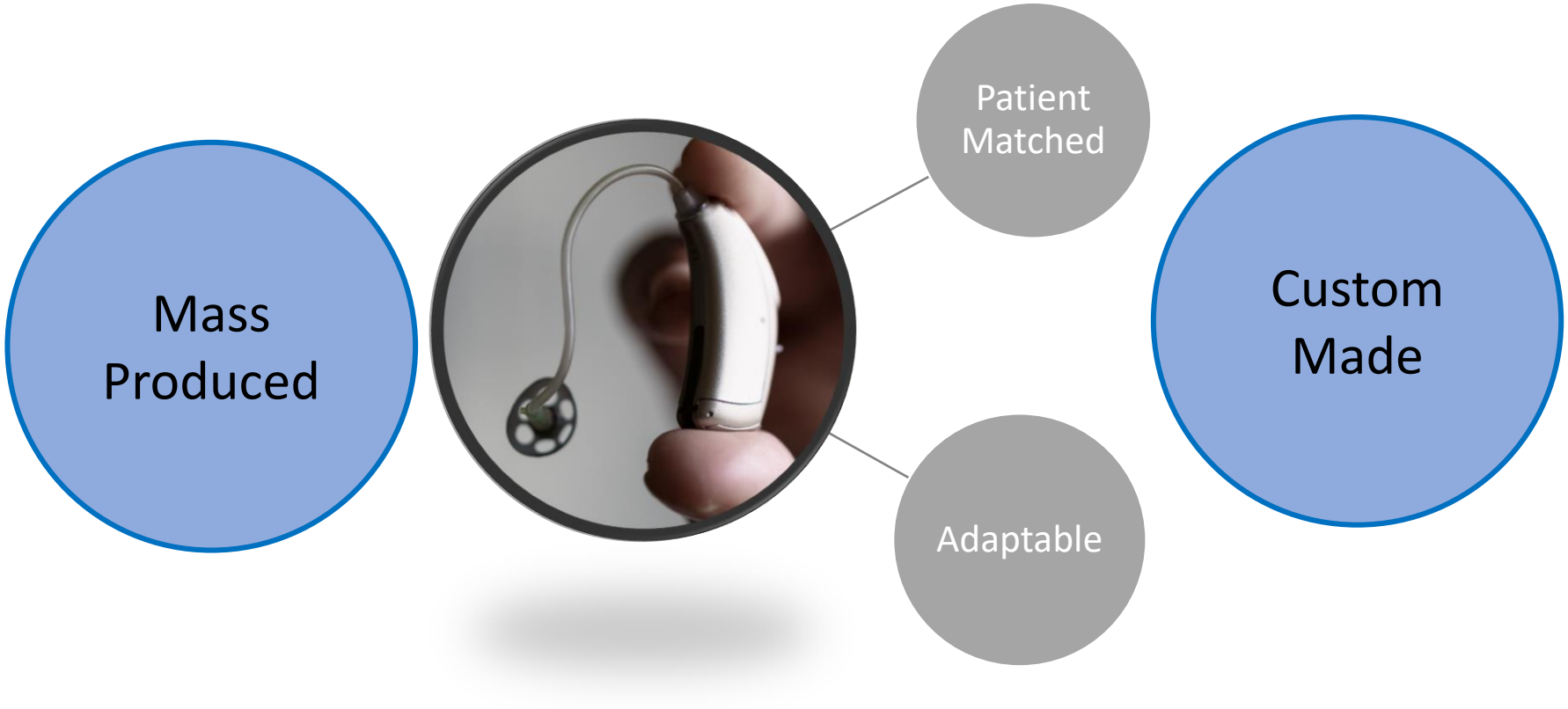
- **Information presented is based on our current understanding of personalised Medical Devices**

- **Subject to change!**



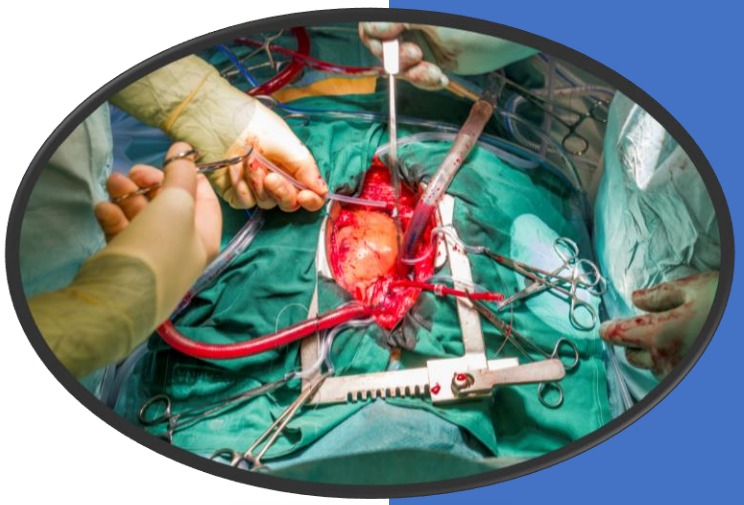
What is a personalised Medical device

personalised medical device – a generic term to describe any of the types of medical devices that are intended for a particular individual, which could be either a custom-made, patient-matched, or adaptable medical device.



Custom-made medical device

- **custom-made medical device** – a medical device that, at a minimum, meets the following requirements:
  - it is intended for the sole use of a particular individual (which could be a patient or healthcare professional); and
  - it is specifically made in accordance with a written request of an authorized professional, which gives, under their responsibility, specific design characteristics; even though the design may be developed in consultation with a manufacturer; and
  - it is intended to address the specific anatomo-physiological features or pathological condition of the individual for whom it is intended.



- Note 1: Medical devices that are patient-matched, adaptable or mass-produced **shall not be considered to be custom-made**.
- Note 2: A custom made device is intended for a case where an individual's specific needs cannot be met, or cannot be met at the appropriate level of performance, by an alternative device available on the market.

Patient-matched medical device

- **patient-matched medical device –** a medical device that meets the following requirements:
  - it is matched to a patient's anatomy within a specified design envelope using techniques such as scaling of the device based on anatomic references, or by using the full anatomic features from patient imaging; and
  - it is typically produced in a batch through a process that is capable of being validated and reproduced; and
  - it is designed and produced under the responsibility of a manufacturer even though the design may be developed in consultation with an authorized healthcare professional.

- **Note 1:** A written request from an authorized healthcare professional may be present; but is not mandatory.
- **Note 2:** The number and type of design inputs in consultation with a healthcare professional may vary depending on the medical devices to be manufactured.
- **Note 3:** The design must remain within the validated parameters of the specified design envelope.

Adaptable medical device

- **adaptable medical device –** a medical device that meets the following requirements:
  - it is mass-produced; and
  - it is adapted, adjusted, assembled or shaped at the point of care, in accordance with the manufacturer's validated instructions, to suit an individual patient's specific anatomo-physiologic features prior to use.

Mass Produced devices

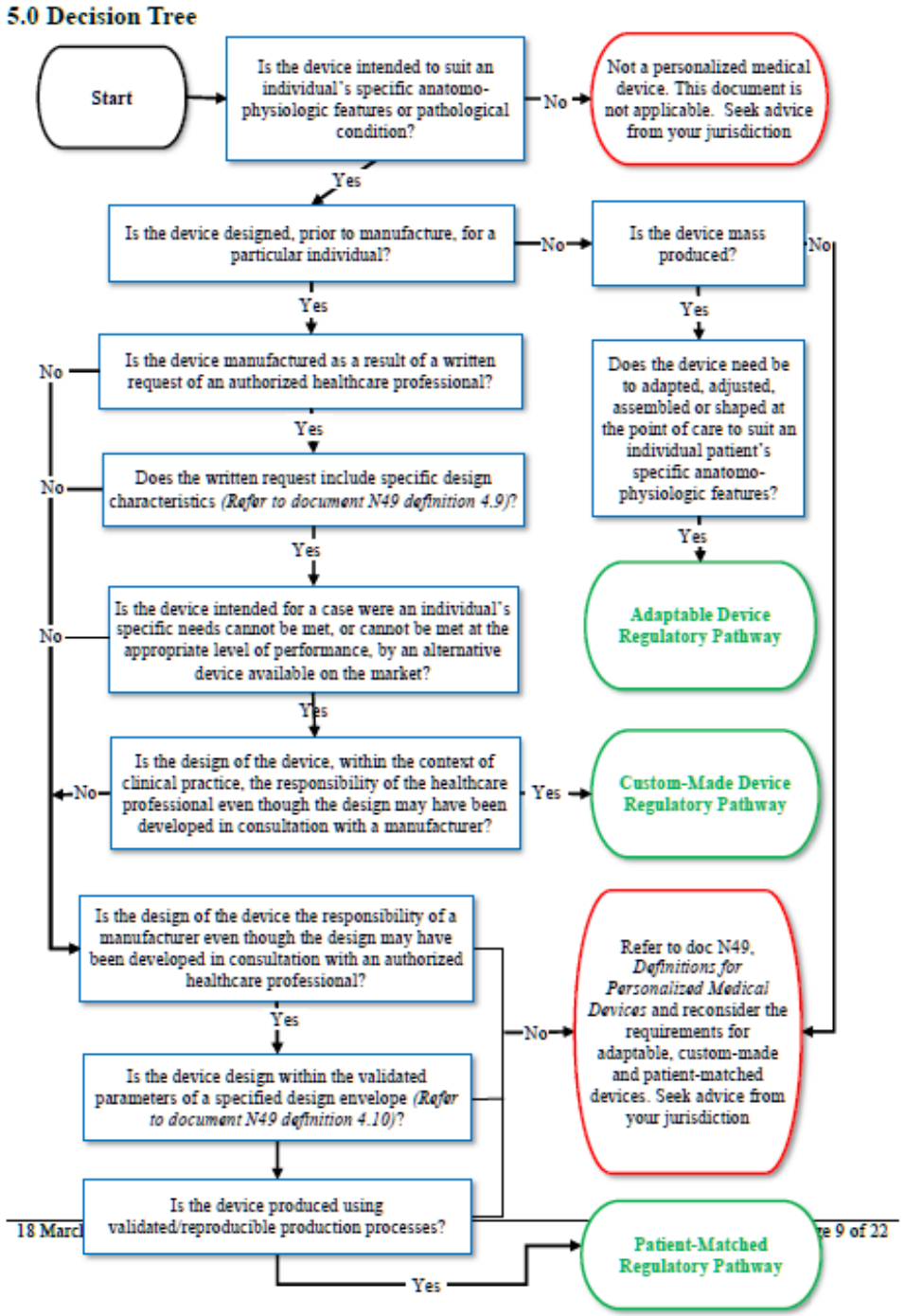
mass-produced devices:

Devices which need to be adapted to meet the specific requirements of any professional user

Devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person

shall not be considered to be custom-made devices

Decision Tree



What's the legislation & guidance documents

MDR 2017/745	MDCG 2021-03	IMDRF/PMD WG/N49 FINAL:2018	IMDRF/PMD WG/N58 FINAL:2020
• Medical Device Regulation	• Q&A Personalised Medical Devices	• Definitions for Personalised Medical Devices	• Personalised Medical Devices – Regulatory Pathways

Requirements

- Ensure all elements of definition are met
- Determine classification of the device
- Assess safety and performance
- Manufacturers are recommended to have a QMS.

Custom Made

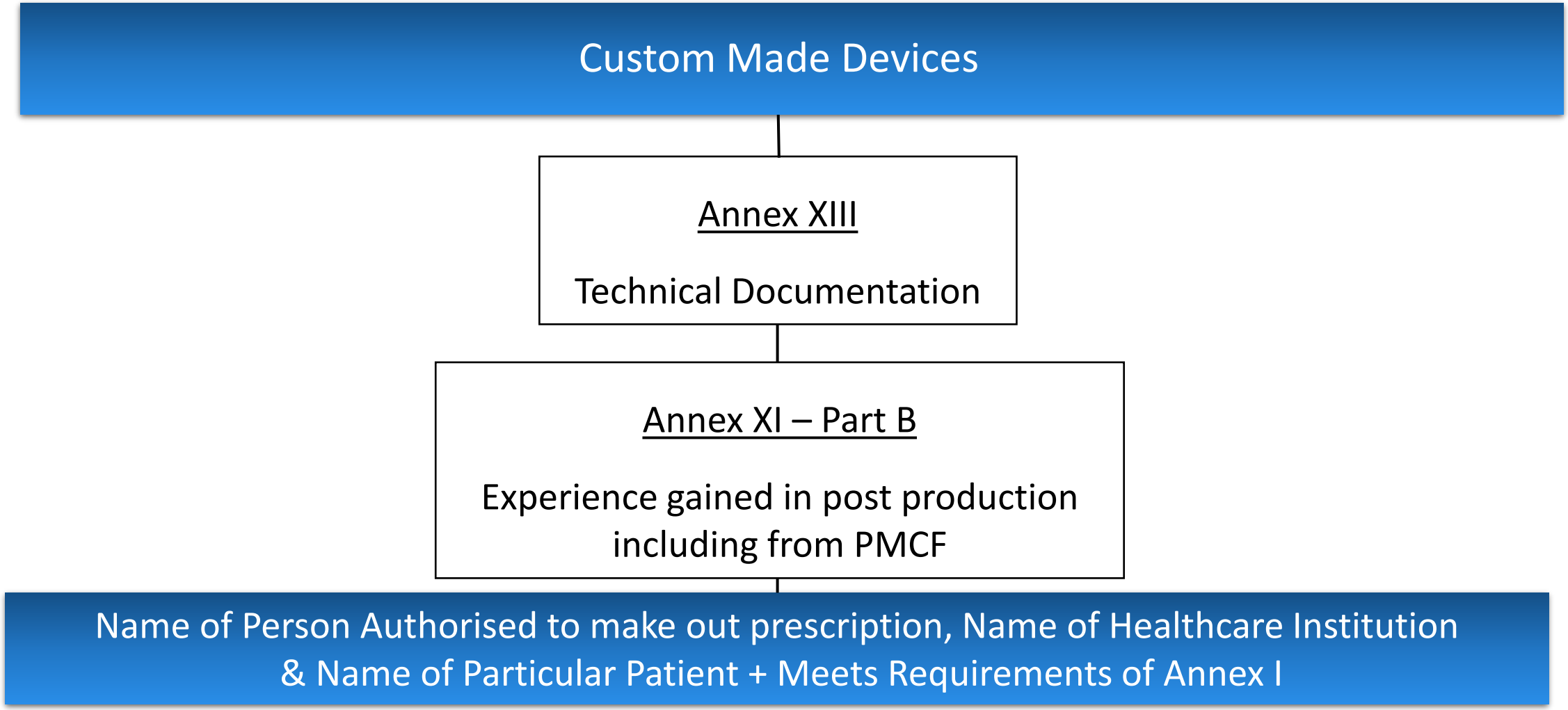
- Mnf is responsible for matching the design of the device to the individual`s anatomy
- Mass-produced
- Correct classification
- Follow usual regulatory requirements
- Meet pre- and post-market regulatory requirements
- Some requirements on manufacturing and record keeping

Patient-matched

- Mass-produced
- Follow the usual regulatory requirements
- Meet pre- and post-market regulatory requirements
- Required to provide **validated** instructions

Adaptable

MDR 2017/745



Article 52 Point 8

Class III Implantable – Custom Made Devices

Article 15 PRRC – experience within a relevant field of manufacturing

Annex XIII

Technical Documentation

Annex IX

QMS

Annex XI – Part A

Production Quality Assurance

Name of Person Authorised to make out prescription, Name of Healthcare Institution & Name of Particular Patient + Meets Requirements of Annex I

Article 27 – No need for UDI

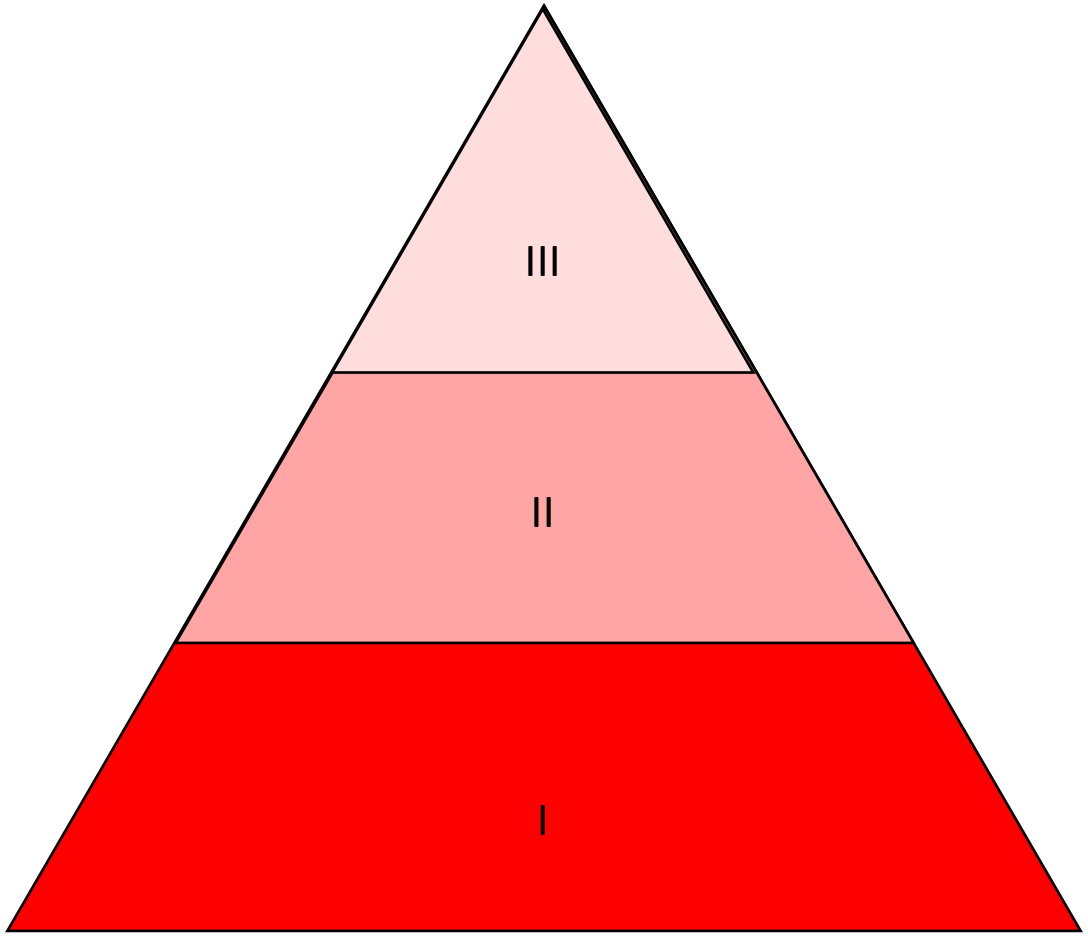
Article 32 – No need for SSCP

No need for CE and NB number

Article 21 – 'Member States may require … a list of devices which have been made available in their territory.'

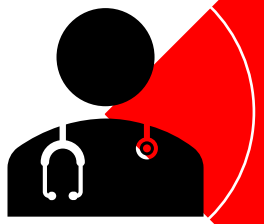
Article 86 – PSUR required for Annex XIII

PRACTICAL ASPECTS OF CLASSIFYING PERSONALISED MEDICAL DEVICES

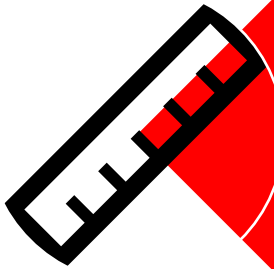


IS MY DEVICE CUSTOM?

Route to conformity;
- Annex XIII
- Class III, Annex XIII + IX chap 1/XI part A



Is **specifically** made in accordance with a **written prescription of any person authorised by national law** by virtue of that person's professional qualifications; which gives

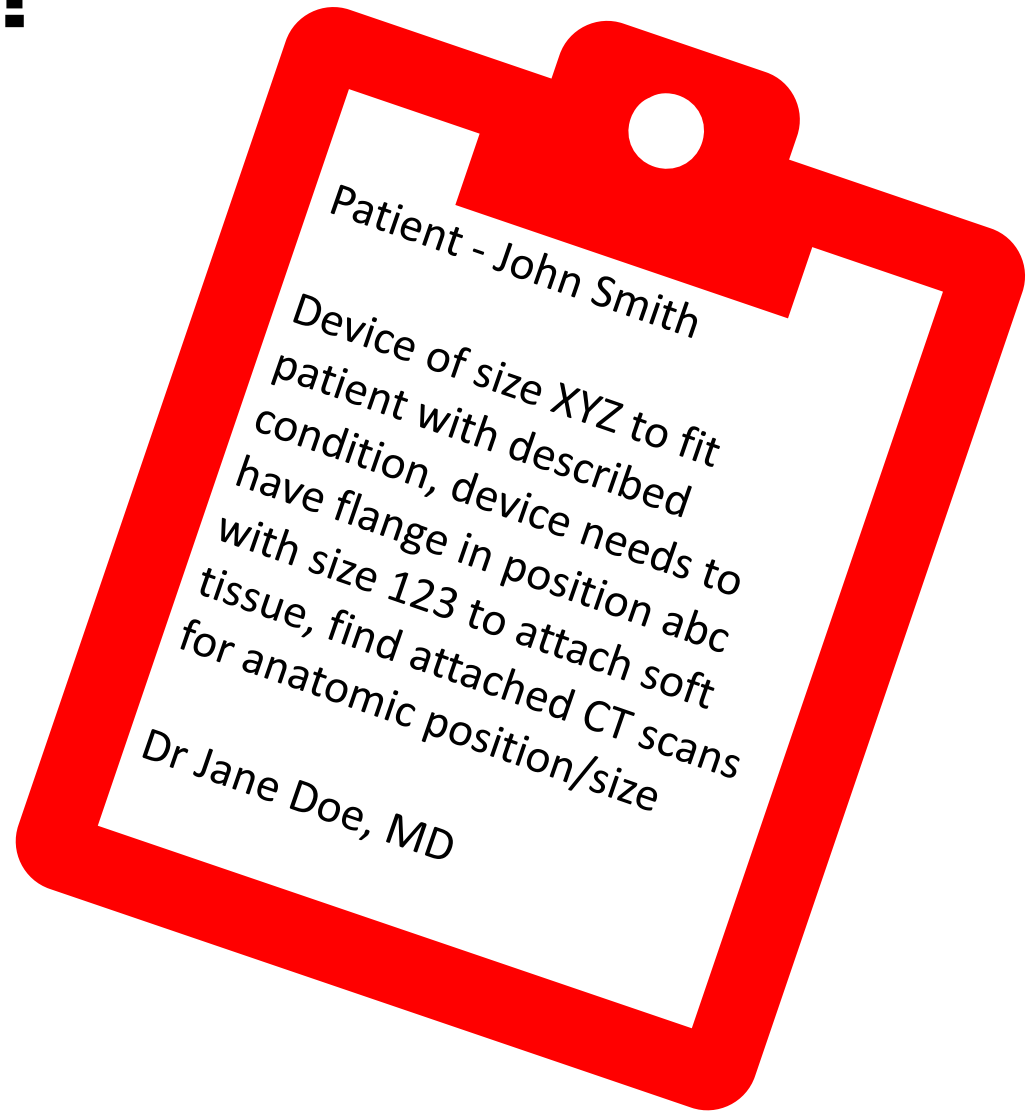


specific design characteristics provided under that person's responsibility; and

is intended for the **sole use of a particular patient exclusively to meet their individual conditions and needs.**

WHAT INFORMATION IS REQUIRED IN A WRITTEN PRESCRIPTION?

- Issued by a qualified person as defined by national law
- Contain name (or pseudonym) of patient
- Specific design characteristics made by the authorised person, unique to the patients anatomic/physiological features and/or pathological condition. May constitute;
  - Models (physical or 3D models)
  - Moulds
  - Impressions
- Note: Dimensions and/or geometric parameters (such as DICOM files from CT scans) are not considered specific design characteristics on their own. Additional measured data or information by the prescribing person is necessary as part of a written prescription in order for the definition of a CMD to be met.



PATIENT MATCHED?

Route to conformity;
- Follow appropriate conformity assessment route for classification of that device.

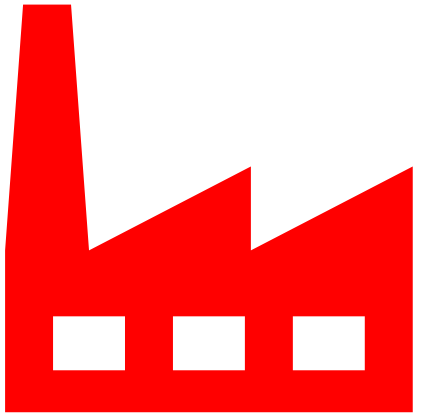
Devices that are developed or altered specifically for a patient but have a defined validated window for which the devices can be produce

- Design is largely driven by the manufacturer – minor modifications to fit specific patient anatomy
- Validated window and well defined restrictions on the design
- Could require patient details from x-ray, CT, MRI to manufacture the devices
- Often “mass produced” large volumes, well defined workflow, manufacturer in control of most of the design and production process although there may be critical features defined or approved by HCP

I 3D print my devices therefore they are not considered "mass produced"

a. True
b. False

MASS PRODUCED?



- My devices are 3D printed
- My devices are produced in a small batch or individually
- My devices are produced by CNC machining or other mass production methods

Focus areas;

- How well validated is the process?
- Who is driving the design features of the device?
- What is the likelihood of exactly reproducing the device?
- Has a bespoke machining program been used?

MISCONCEPTIONS ABOUT CLASSIFYING AS CUSTOM?

There is not a number of devices that can be produced before they are considered “standard” components

- A custom device must be “intended for the **sole use** of a particular patient **exclusively** to meet their individual conditions and needs”

Low volume devices or devices for uncommon clinical conditions are not considered to be custom devices unless they meet the definitions of a custom made device.

3D printing can be used as a “mass production” process

Mass production methods don’t mean a device is mass produced e.g. multiaxis CNC machining

The presence of a prescription alone does not make the device custom made

Decision tree useful for aiding decision making – Section 5, IMDRF/PMD WG/N58FINAL:2020

IS MY DEVICE CUSTOM?

I am a manufacturer with an implant design that has well defined characteristics that I can grow/shrink to fit a specific patient. There is a maximum/minimum size for the device and the device can grow/shrink within the size range. Patent specific data such as CT or MRI will be used to establish the size of the device.

Is this a custom made device?

No

Having well defined characteristics implies that the prescription writer does not have control of the design parameters of the device. The provision of anatomic data alone does not meet the requirement of a custom made device. This is likely a patient matched.

IS MY DEVICE CUSTOM?

I provide a device as standard product of an antibiotic loaded device, however, upon request I can change the antibiotic to a different antibiotic, the type and concentration of the antibiotic is defined by the manufacturer. However the request is made via “prescription”

Is this a custom made device?

No

Having predefined options for “non-production” devices does not meet the requirement that the design is controlled by the HCP or that the device is unique for the anatomy or condition of the individual patient. In this instance the device appears to be a low volume production device and should follow the standard route to conformity.

IS MY DEVICE CUSTOM?

A manufacturer provides a service where a HCP may request a device that is specific to the patient anatomy, there are no limitations on the device and the HCP may define the critical features of the device. The manufacturer provides design assistance with regard to limitations relating to mechanical and material limitations, it also allows for design of certain elements to be compatible with standard devices.

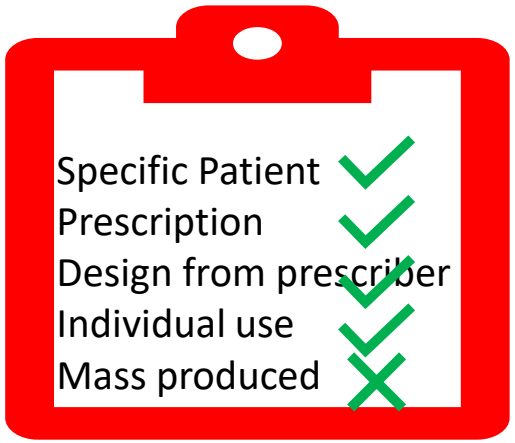
Is this a custom made device?

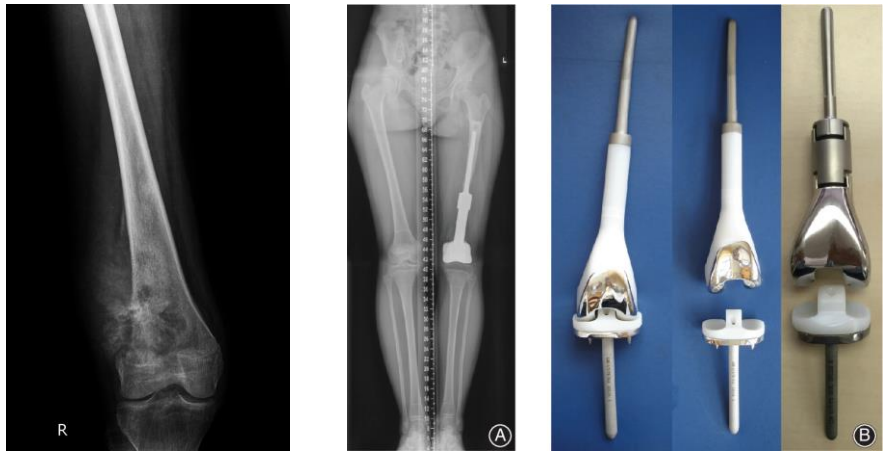
Yes

In this instance the device is largely unlimited in its design scope and the HCP is providing design critical requirements. The manufacturer is still ultimately responsible and therefor should restrict the design based upon the risk management activities to ensure safety and performance. Standard certified devices may be used as a component or compatible device with custom made devices.

DEVICE EXAMPLES – HOW SHOULD I CLASSIFY THIS DEVICE?

An orthopaedic device required for a specific patient. The request has been made by the surgeon who has created a prescription. Within the prescription 3D scans have been provided and the surgeon has provided specific details about the size and shape of the device that is required in order to treat the patient. The manufacturer provides expertise in implant design and largely specifies many of the technical requirements of the device. The device will be manufactured utilising CNC machining. The manufacturer does not place limitations upon the device outside of requirements necessary for its safety.



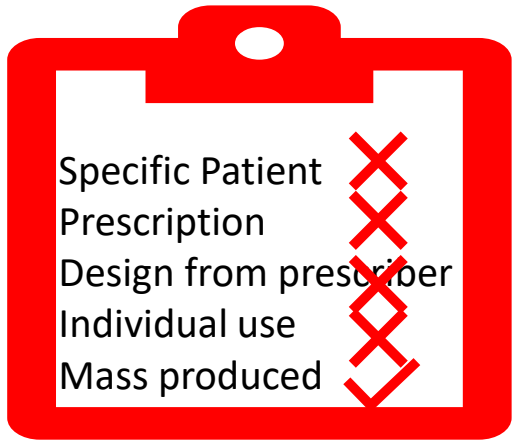


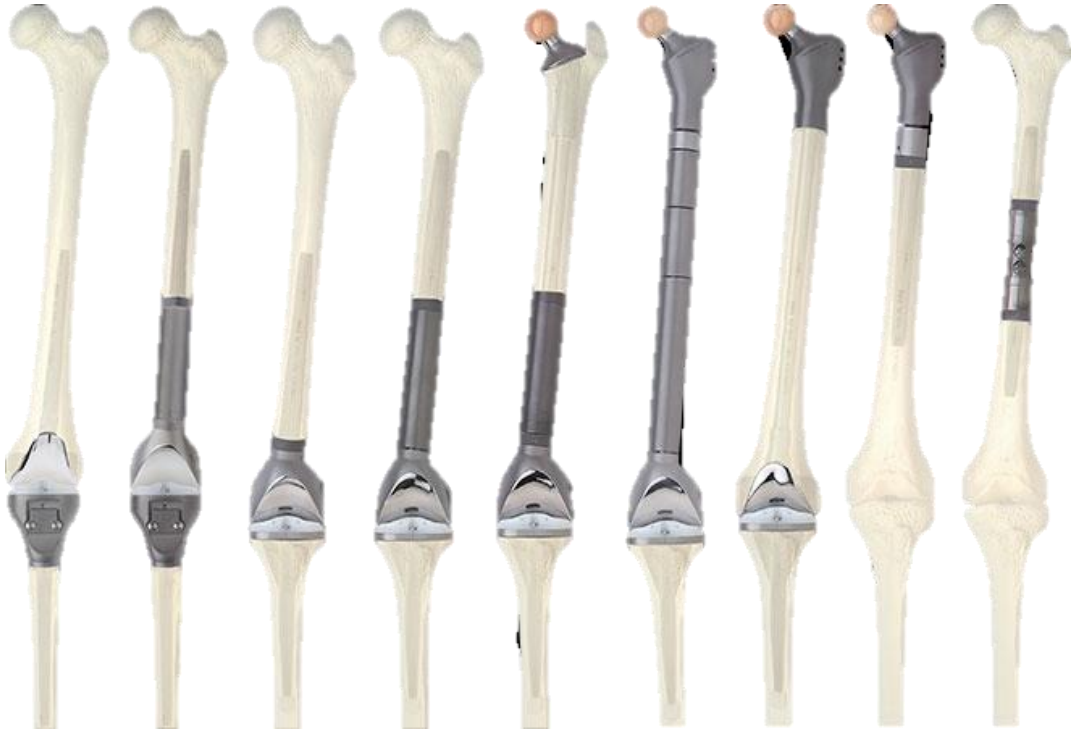
Custom

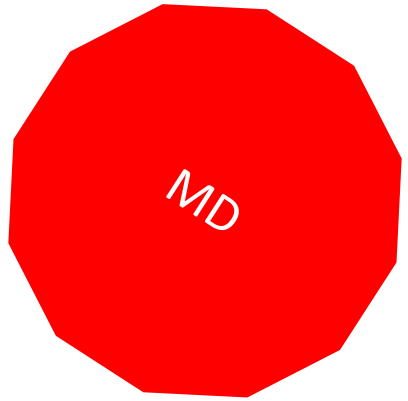
https://onlinelibrary.wiley.com/doi/10.1111/os.12525; **Limb Salvage Using Non-hinged Endoprosthesis and Staged Correction of Leg-length Discrepancy for Children with Distal Femoral Malignant Tumors**

DEVICE EXAMPLES – HOW SHOULD I CLASSIFY THIS DEVICE?

A highly modular system of standard components that is available off the shelf. These devices can be purchased directly from the manufacturer by the surgeon and the surgeon can treat a specific patient condition with the options provided.







https://www.linkorthopaedics.com/us/for-the-physician/products/limb-salvage

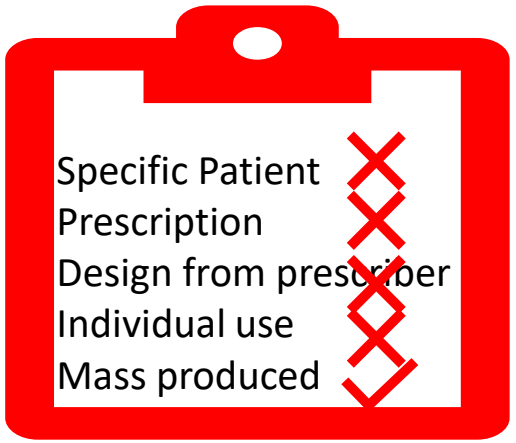
DEVICE EXAMPLES – HOW SHOULD I CLASSIFY THIS DEVICE?

A dental bar designed to fit a particular patient. The dentist will provide specific 3D scans or impressions for the device. The manufacturer designs the device to fit the provided scans/impressions and provides design to the dentist for final approval. The dentist may provide details of the dental implant system the device will be used with. The manufacture then produces the bars and provides them to the dentist for combination with an prosthetic and final implantation.

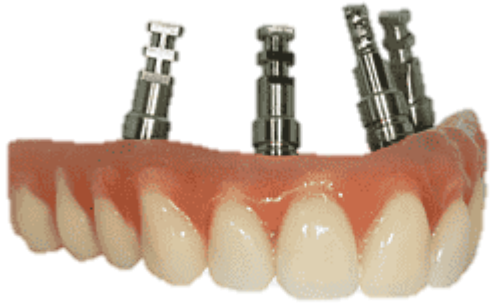
https://www.3dsystems.com/implant-suprastructure/bars

DEVICE EXAMPLES – HOW SHOULD I CLASSIFY THIS DEVICE?

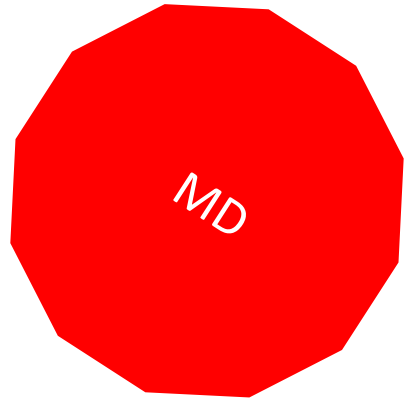
Materials used to create dental prosthetics. A precursor material is utilised as an intermediate to create a device for an individual patient. The materials are individually tailored on the request of a dentist to meet the particular needs of the patient. The final device is often created by a 3rd party using artisanal techniques.



https://bristolcadcam.com/shop/consumables/materials/pmma/pmma/

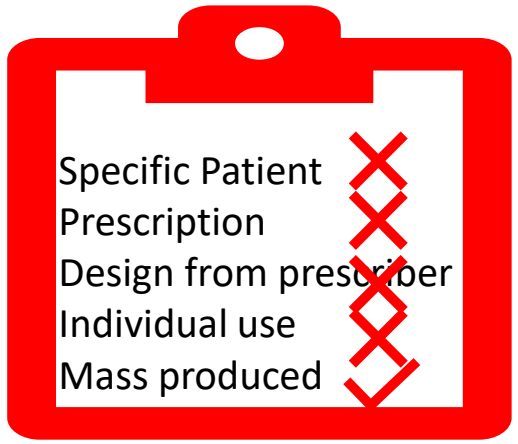


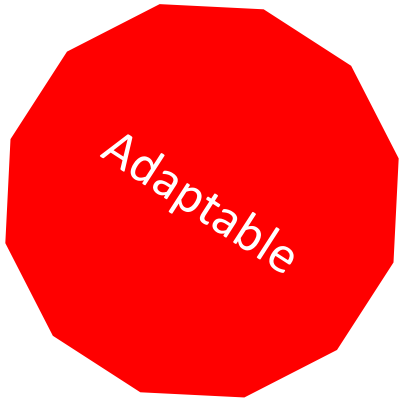
https://www.pngwing.com/en/free-png-ddswi



DEVICE EXAMPLES – HOW SHOULD I CLASSIFY THIS DEVICE?

A cranial mesh that can be formed to an individual patient anatomy. The mesh can be shaped and trimmed to match the individual patient. The device is produced by the manufacturer for purchase by the end user for a specific patient.





https://twitter.com/depuysynthes/status/1050008087673925633

DEVICE EXAMPLES – HOW SHOULD I CLASSIFY THIS DEVICE?

A cutting guide to allow precise placement of an orthopaedic implant to a specific patient. The surgeon provides CT scan data to the manufacturer and may provide specific details about preferred positioning and orientation of the final implants. The manufacturer produces the guides to their own specification and are designed to be utilised with their implants.

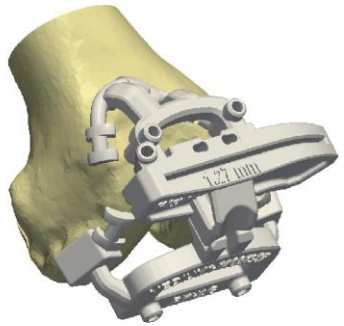


Fig. 1 Femur cut guide

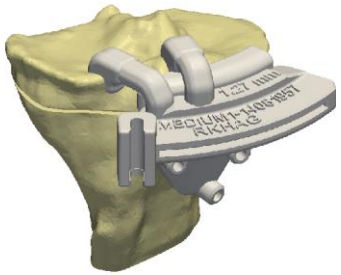
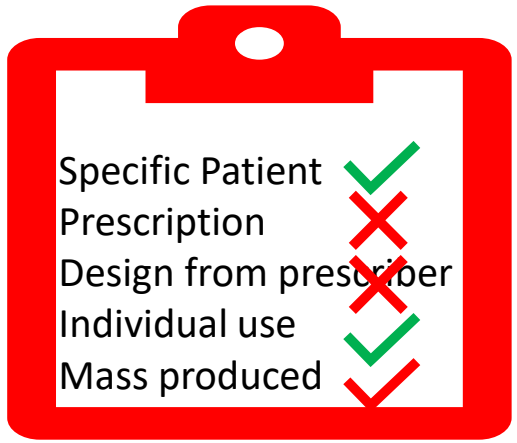
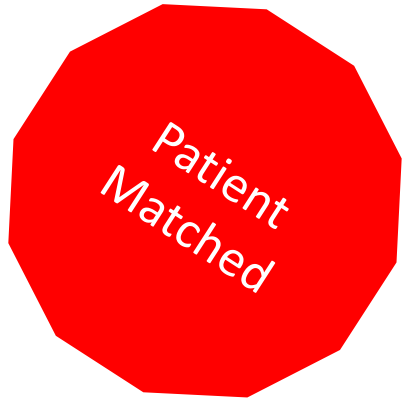
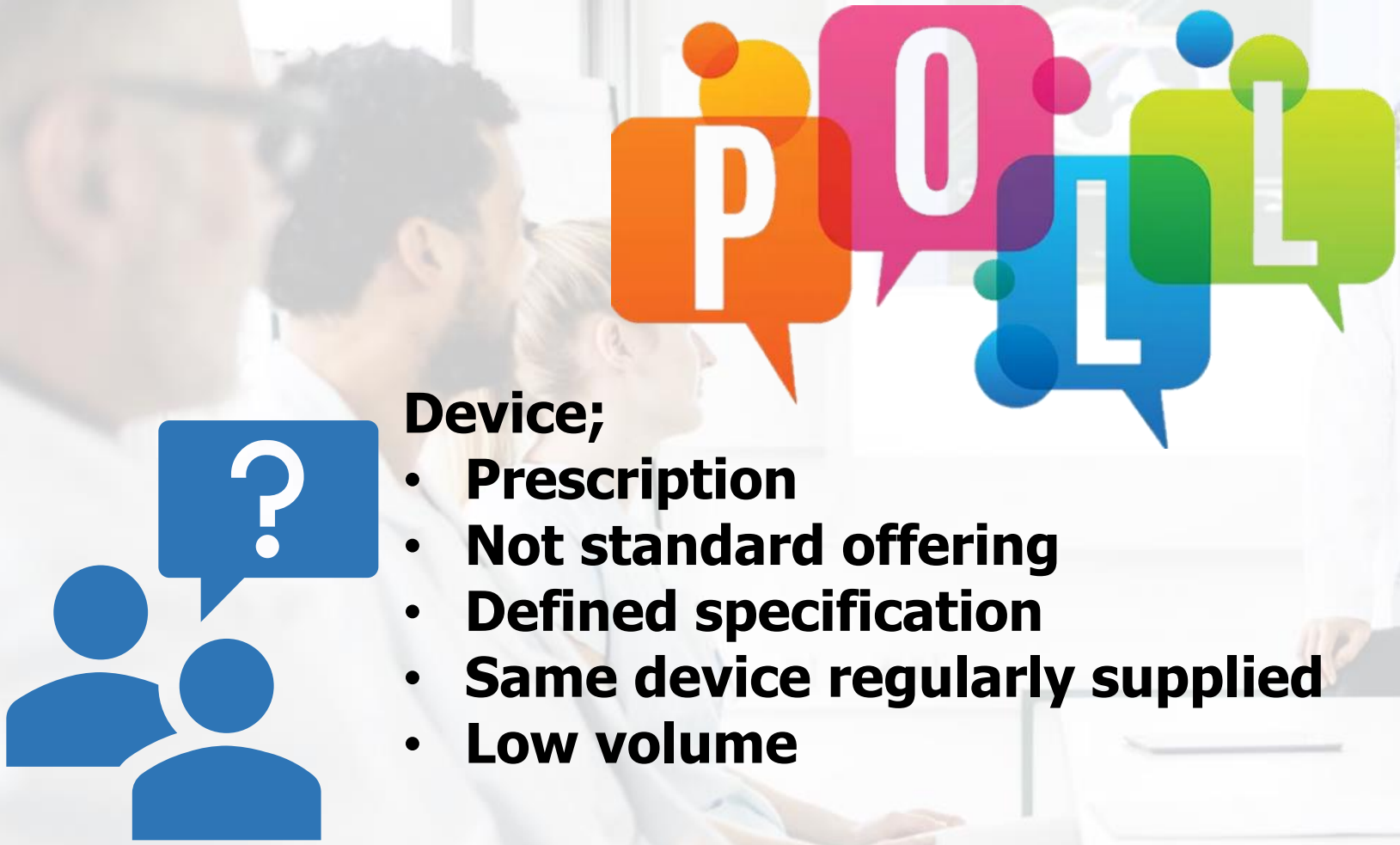


Fig. 2 Tibia cut guide

https://www.semanticscholar.org/paper/Clinical-validation-of-novel-patient-specific-cut/c0ae4e8ed758cc949eb4eff3d66b1c93eff0fb3d







Device;

- **Prescription**
- **Not standard offering**
- **Defined specification**
- **Same device regularly supplied**
- **Low volume**

Is this a custom made device?

a. Yes
b. No

Summary

- Requirements for custom made devices Annex XIII MDR
- Useful guidance
  - MDCG 2021-3
  - IMDRF/PMD WG/N58 2020
  - IMDRF PMD WG/N49 2018
- Still grey areas with certain devices
- If in doubt talk to NB or BSI scheme manager about your proposed route to conformity
- Document your rationales

BSI Medical Devices – Use Our Resources

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

Brochures, Guides and Documents

MDR guidance

MDD Best Practice Guidelines >
MDR Best Practice Guidelines >
MDR Mapping Guide >
MedDev 2.7.1 Rev 4 changes >
MDR Conformity Routes >
MDR Readiness Review >

Webinars

MDR Conformity Assessment Routes webinar

MDR - What we know

Download the presentation >

White Papers and Articles

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.

Training Resources

Medical devices regulation (MDR)	
Transition from MDD to MDR	1 day
Technical Documentation for CE - Marking	1 day
Requirements of MDR for CE - Marking	1 day
Implementing of MDR for CE- Marking	3 days

Further courses for medical devices manifacturers	
Medical Device Single Audit Program (MDSAP)	2 days
ISO 14971 Risk Management	1 day
Creating and Maintaining Technical Files	1 day
Post-market Surveillance and Vigilance	1 day
Clinical Evaluation for Medical Devices	1 day
Process Validation for the Medical Device Industry	1 day
Introduction to Medical Device Software	1 day

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https://www.linkedin.com/showcase/bsi-medical-devices/

bsi. Inspiring trust for a more resilient world.

Questions?

Thank you for joining today

Judith Prevoo

Regulatory Lead NL

Tim Marriott

Technical Specialist and Scheme Manager O&D