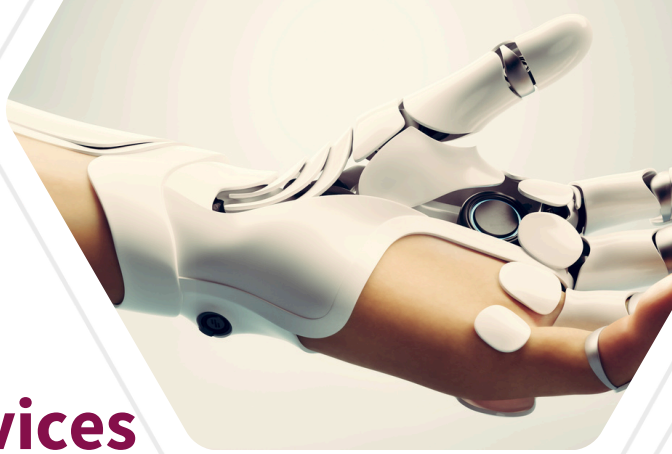
ASPHALION
MedTech

Personalized Medical Devices

ASPHALION MedTech



Personalized Medical Devices

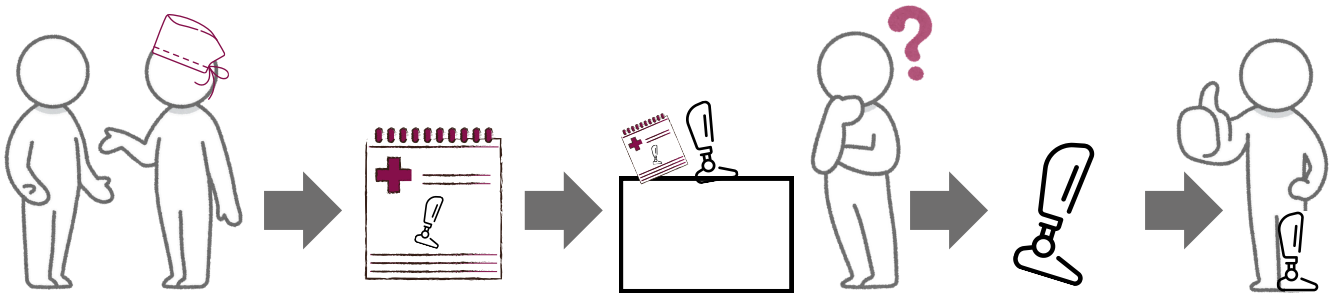
Personalized medical device is a generic term to describe any of the types of medical devices that are intended for a particular individual, which could be either a **custom-made, patient-matched**, or **adaptable medical device**.

Personalized medical devices

1. **Custom-made device**
2. **Patient-matched device**
3. **Adaptable medical device**

1 A custom-made device is defined as any device that:

- Is specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications.
- Gives specific design characteristics provided under that person's responsibility.
- Is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.



Individual patient | Authorised person | Written prescription | Manufacture | Custom-made device | Supplied to patient

www.asphalion.com
info@asphalion.com | +34 93 238 59 45

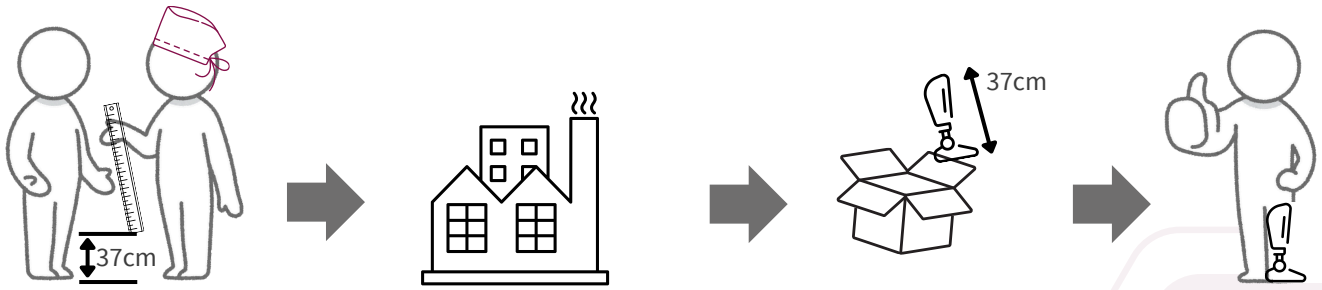
ASPHALION MedTech

2 A **patient-matched device** is defined as 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.
- It is typically produced in a batch through a process that is capable of being validated and reproduced.
- 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.

Different from a custom-made device, these devices are typically produced in batches or through mass-production and a written prescription from an authorized healthcare professional may be present; but is not mandatory.

The design of the patient-matched device must remain within the validated parameters of the *specified design envelope*.



Patient specific measurements made

Manufacture of an existing design to requested specification

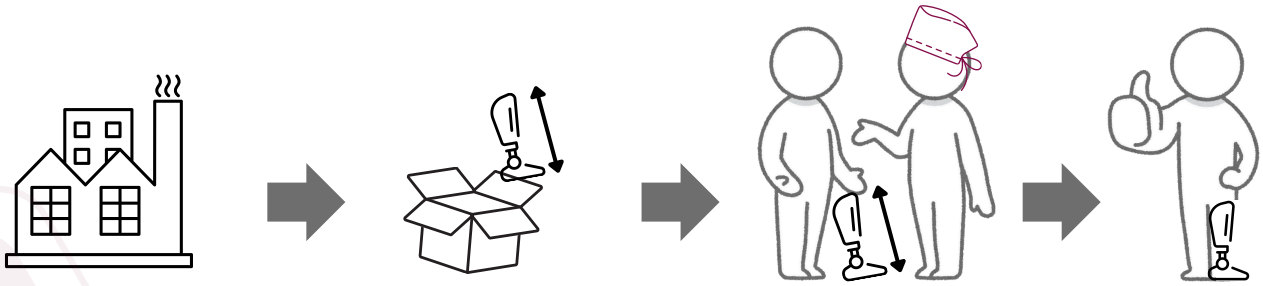
Patient matched device shipped to user

Supplied to patient

3 An **adaptable medical device** is a medical device that meets the following requirements:

- It is mass-produced.
- It is adapted, adjusted, assembled or shaped at the point of care, in accordance with the manufacturer's validated instructions (those necessary for the adaptation of the device and should not be confused with instructions for use), to suit an individual patient's specific anatomo-physiologic features prior to use.

www.asphalion.com
info@asphalion.com | +34 93 238 59 45



Key definitions

- *Specific design characteristics*: unique design specifications, necessary to produce custom-made devices, that are based on an individual's specific anatomo-physiological features and/or pathological condition; and that cannot be proposed by a manufacturer without the involvement of a healthcare professional.

- *Written prescription*: it must be issued by a qualified person authorised by national law and it should contain at minimum:
    - The name of the patient (or pseudonym if relevant),
    - Specific design characteristics made by the authorised person which are unique to the patient's anatomic-physiological features and/or pathological condition.

- *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 (such as the thickness and trajectory of a plate, the number, type and positions of fixation screws, choice of material) by the prescribing person shall also be provided for as part of a written prescription.

- *DICOM files*: patient imaging files, typically produced by computed tomography (CT) or magnetic resonance (MR), that are saved in the Digital Imaging and Communications in Medicine (DICOM) format.

- *Specified design envelope*: minimum and maximum dimensions, mechanical performance limits, and other relevant factors that characterize a medical device for production purposes, which may be based on a standard device template model.

- *Mass-produced medical device:* a medical device that is based on standardized dimensions/designs; that is not designed for a particular individual; and that is typically produced in a continuous production run or homogenous batch.

ASPHALION MedTech

- *Batch*: one or more components or finished devices that are produced using the same lot of raw material, the same method of manufacture, having the same probability of chemical or microbial contamination, and that are intended to have uniform characteristics and quality within specified limits.

Comparative Table	Custom-made devices	Patient-matched devices	Adaptable medical devices
Written prescription	Mandatory (by person authorised by national law)	May be present, but is not mandatory	Not necessary
Exclusive use of a specific person	Yes		No
Product responsibility	Person authorized by national law who made the written prescription	Manufacturer	
Design specifications	Specific to an individual patient's anatomy and needs	Based on individual patient measurements or images	Generic design adaptable to a range of patients
Production	Specially manufactured at the written prescription	Usually in a batch through a process that is capable of being validated and reproduced	Mass-production
MDR 2017/745	Custom-made device - Article 2(3)	Normal medical device - Article 2(1)	

www.asphalion.com
info@asphalion.com | +34 93 238 59 45

ASPHALION MedTech

Relevant considerations

Custom-made devices

- Conformity assessment procedure described in **Annex XIII of MDR**.
- Accompanied by **an Annex XIII statement**, available to the particular patient or user identified by a name, an acronym or a numerical code. Required instead of a declaration of conformity.
- Manufacturers **are exempt from device UDI registration, assignment and labelling requirements**. Appointment of a PRRC is mandatory per Article 15 of MDR; registration in EUDAMED not necessary.
- PMS: **a PMS report for Class I devices and a PSUR for class IIa, IIb and III** must be established by the custom-made device manufacturer. **SSCP is not required**.
- A conformity assessment procedure covering QMS certification by a notified body (Chapter I of Annex IX or Part A of Annex XI of MDR) is applicable to **Class III implantable custom-made devices**; certificates must be registered in EUDAMED. For these devices, PSURs are not required to be sent to notified bodies but must be part of the device documentation.

Patient-matched devices

- **Variables within the design envelope are predetermined by the manufacturer**.
- Although design inputs may be provided by authorized persons (medical imaging or anatomic references), **manufacturers are responsible for matching the design of the device to the individual's anatomy, within the design envelope**, based on techniques such as scaling.
- Manufacturers must identify the **maximum performance** limits and limiting configurations (parameters and manufacturing variables).
- Manufacturers must keep records of written requests and patient-matching information, adhering to applicable legal retention periods

Adaptable MDs

- Manufacturers should be required to **provide validated instructions that explain how to adapt, adjust, assemble, or shape the device**.
- Manufacturers may place requirements on the individual or entity who will be undertaking the adaptation (the adapting entity), for example, **requiring that verification testing be conducted and that records be maintained**. Manufacturers may also consider the need for training of the adapting entity.

ASPHALION MedTech

Reference Guidelines

- **IMDRF/PMD WG/N49 FINAL**: 2018 Definitions for Personalized Medical Devices.
- **IMDRF/PMD WG/N58FINAL**: 2020 Personalized Medical Devices - Regulatory Pathways.
- **Regulation (EU) 2017/745 on medical devices.**

Need help? Contact us!

www.asphalion.com

info@asphalion.com

+34 93 238 59 45

Author

Koldo García de Acilu
Medical Device Consultant