

Personalized Medical Devices Working Group Update

Working Group Chair(s):

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Personalized Medical Devices Working Group (PMD WG)

Current Status: Closed since the 27th Management Committee (MC) meeting in Tokyo, Japan in March 2025

Members (prior to closure): Argentina, Australia, Brazil, Canada, China, El Salvador, Europe, Japan, Paraguay, Saudi Arabia, Singapore, South Korea, UK, USA, Taiwan, GHWP

Strategic Plan: Priority 1 – Premarket: develop a risk calibrated regulatory approach for innovations and promote harmonized pre-market review requirements for medical devices.

Task: MC agreed that before closure TGA will develop an eLearning module for IMDRF N49 document



Publications – Guidance Finalised by PMD WG

1. Definitions for Personalized Medical Devices ([N49](#))

Published November 2018



N49

2. Personalized Medical Devices – Regulatory Pathways ([N58](#))

First published April 2020

Revised version published September 2023



N58

3. Personalized Medical Devices – Production Verification & Validation ([N74](#))

Published April 2023



N74



IMDRF PMD N49 – Publication of eLearning module

Objective: To support the adoption and consistent interpretation of the IMDRF PMD documents



Personalized Medical
Devices eLearning Module

The cover features a blue and white color scheme with a close-up image of a medical device on the right. The title 'Definitions for Personalized Medical Devices from the IMDRF' is prominently displayed in white text. Below the title is a white button with the text 'START COURSE'. At the bottom, the IMDRF logo (a globe) and the text 'IMDRF International Medical Device Regulators Forum' are shown. Additional information includes 'Version 2.0', 'Publishing date: February 2026', and 'Content owners: International Medical Device Regulators Forum | IMDRF'.

Published on the IMDRF website



Key Features

- Easy access and navigation
- No login required
- Plain-English content
- Examples drawn from published PMD documents
- Takes approximately 10-15 minutes to complete
- Includes knowledge test component

Note: This training module is not integrated with any Learning Management System. As a result, user activity and test scores are not recorded.

In this course, we will cover the following topics:

- ≡ Introduction
- ≡ Personalized v Mass-Produced Medical Devices
- ≡ Patient Matched Medical Device (PMMD)
- ≡ Custom-Made Medical Device (CMMD)
- ≡ Adaptable Medical Device
- ≡ Key Takeaways
- ≡ Knowledge Test
- ≡ Course Completion
- ≡ Disclaimer



Screen shots

Personalized Medical Devices

A generic term to describe any of the types of medical devices that are intended for a particular individual.

This could be either a custom-made, patient-matched, or adaptable medical device.



Example:

A maxillofacial plate that is designed using a patient's CT imaging data and 3D-printed to fit the exact shape of a facial bone defect.



Screen shots



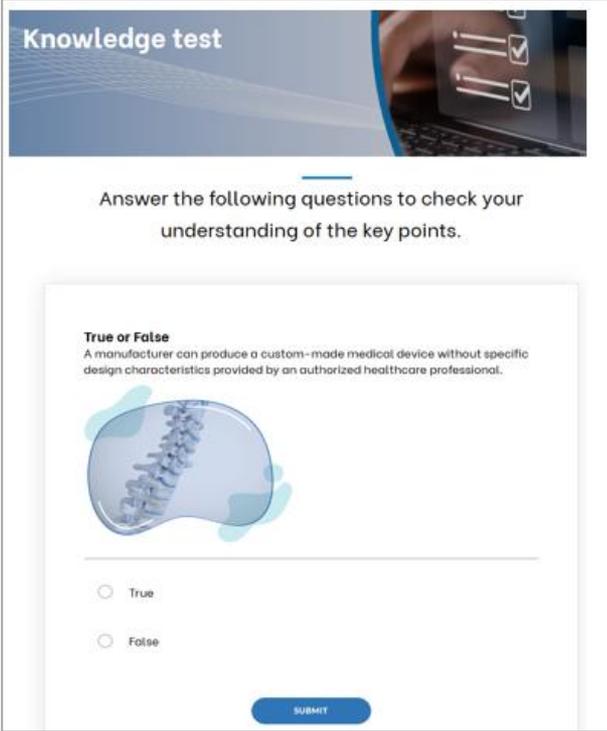
A patient-matched medical device is:

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



Knowledge Test Component

- Learning-focused, not assessment-based
- Interactive questionnaires
- Multiple attempts allowed
- Easy navigation back to learning materials
- No pass/fail scores!



The screenshot shows a digital interface for a 'Knowledge test'. At the top, there's a header with the title 'Knowledge test' and a background image of a hand using a laptop. Below the header, a blue horizontal line is followed by the instruction: 'Answer the following questions to check your understanding of the key points.' The main content area is a white box containing a 'True or False' question. The question text is: 'A manufacturer can produce a custom-made medical device without specific design characteristics provided by an authorized healthcare professional.' Below the text is a 3D illustration of a human spine. At the bottom of the question box, there are two radio button options: 'True' and 'False'. A blue 'SUBMIT' button is located at the bottom right of the question box.

Knowledge test

Answer the following questions to check your understanding of the key points.

True or False
A manufacturer can produce a custom-made medical device without specific design characteristics provided by an authorized healthcare professional.

True

False

SUBMIT

