IMDRF International Medical Device Regulators Forum

Personalized Medical Devices Working Group 2020 Update

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Working group overview

Working group rationale:

Technology has progressed to where it is now possible to ‘mass produce’ individualised medical devices, for example, 3D-printing of devices based on patient CT scan data.

Original GHTF documentation does not adequately address these types of devices.

Working Group Meeting in Canberra
October 2019

Work item timeline

2018	November 2018: Published N49—Definitions for Personalized Medical Devices
2020	March 2020: Published N58—Personalized Medical Devices—Regulatory Pathways (Approved)
TBD	Proposed NWIE—Personalized Medical Devices—Considerations for validating design envelopes and personalized medical device production systems

Benefits of reform

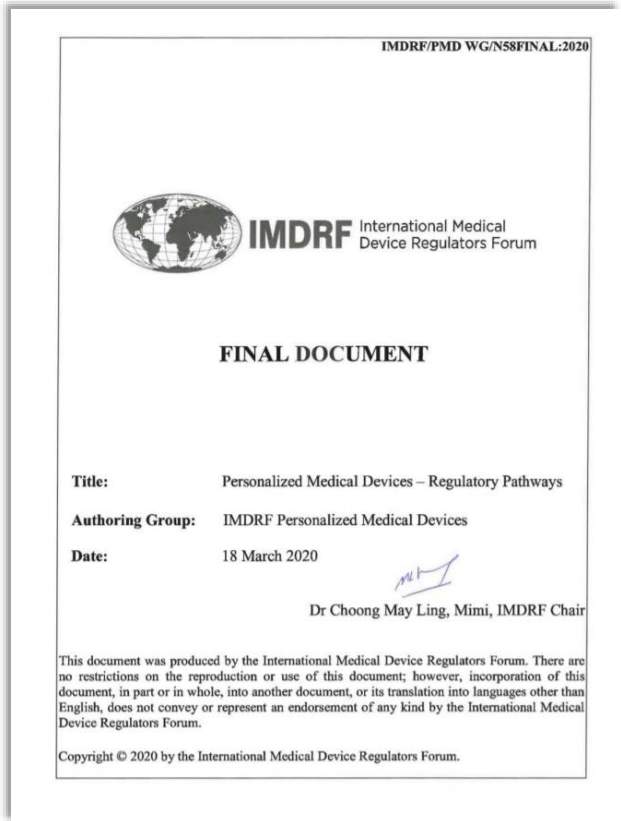
- Addresses an emerging trend towards personalized treatments in the medical devices sector.
- Ensures an appropriate level of regulatory oversight is undertaken.
- Leads to harmonisation of requirements for safety, performance and manufacturing of these products.
- Provides a basis for consistent and transparent requirements across multiple jurisdictions.
- Aligns with IMDRF Strategic Priorities.

Final regulatory pathways document (N58)

Published March 2020

The goal of this project was to develop a technical document that provides recommendations to support a harmonised approach to regulating medical devices that are manufactured for individuals.

- Two-month public consultation held 24 May 2019 through 24 July 2019
- 17 submissions including from Australia, Canada, Europe, Singapore, Taiwan, USA
- 150 Individual comments
- Working group meeting in Canberra October 2019 to review comments and update the document
- Final document delivered and agreed by IMDRF Management Committee



IMDRF/PMD WG/N58FINAL:2020

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Personalized Medical Devices – Regulatory Pathways

Authoring Group: IMDRF Personalized Medical Devices

Date: 18 March 2020

Dr Choong May Ling, Mimi, IMDRF Chair

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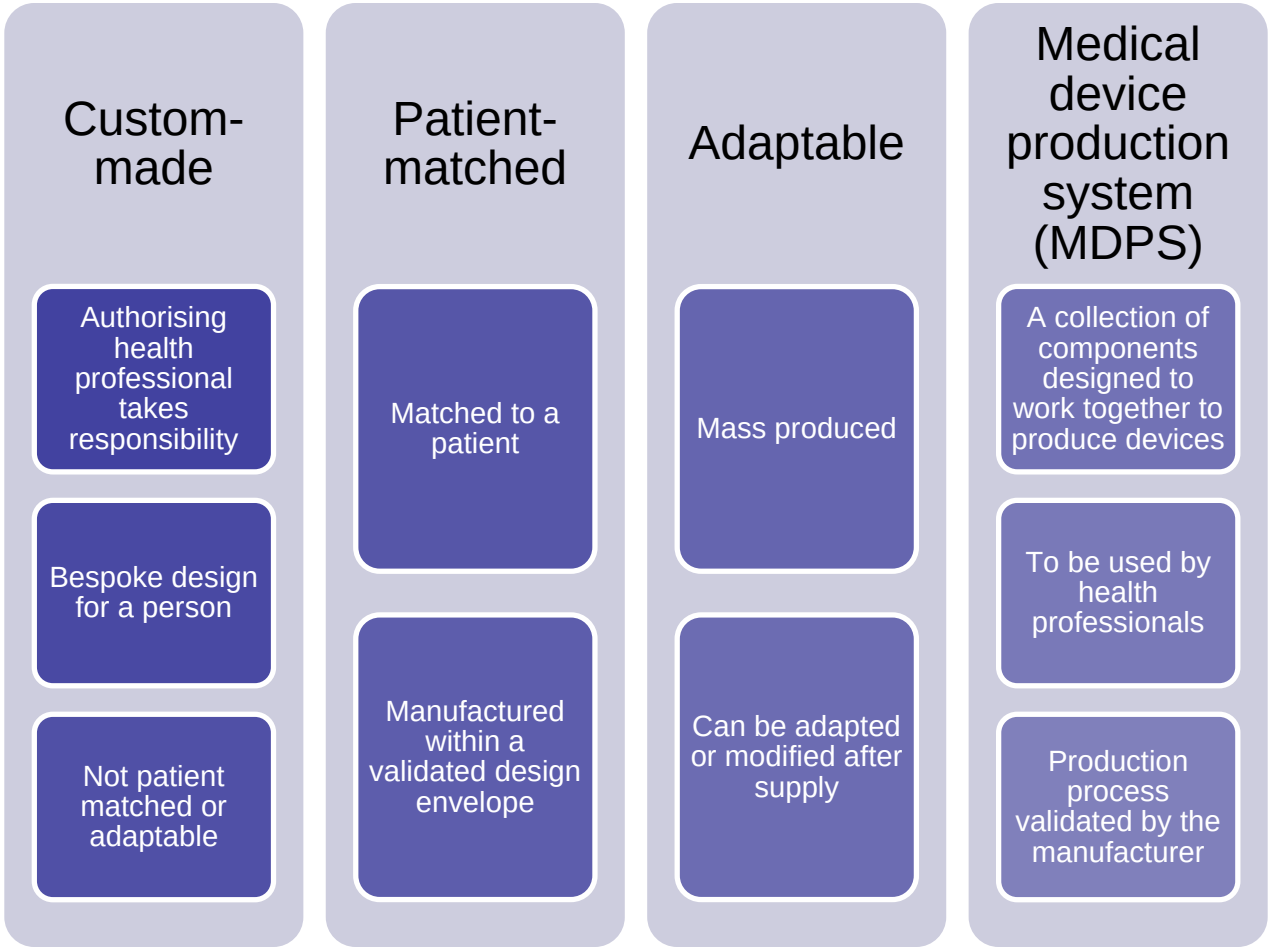
Regulatory pathways



Regulatory pathways

Custom-made medical devices

- Highest level of detail
- Recognises unique pathway for custom-made devices

Patient-matched medical devices

- Reliance on usual regulatory requirements, according to the device regulatory classification
- Focus on validation of design envelope

Adaptable medical devices

- Reliance on usual regulatory requirements, according to the device regulatory classification
- Focus on validated instructions for the adaptable features

Medical device production system (MDPS)

- Considered to be a medical device in its own right
- Reliance on usual regulatory requirements, according to the device regulatory classification of device produced
- Focus on validation of production process

Annexes

Annex 1—Additive and subtractive manufacturing considerations

- Introduces MDPS
- Clarifies status of raw materials for additive manufacture vs materials that are medical devices

Annex 2—Considerations for point-of-care manufacture

- Manufacturing under special arrangements (e.g. exemptions)
- Using medical device production systems
- Fully regulated manufacturing as per the GHTF/IMDRF model

Next steps—PMD validation guidance

- for consideration by the IMDRF Management Committee in 2020

Thank you