



Personalised Medical Devices Working Group

Chair: Australia

Members: Argentina, Brazil, Canada, China, El Salvador, Europe, Japan, Paraguay, Saudi Arabia, Singapore, South Korea, UK, USA, GHWP



Publications:

Definitions for Personalized Medical Devices ([IMDRF/PMD WG/ N49](#))

Published November 2018

Personalized Medical Devices – Regulatory Pathways ([IMDRF/PMD WG/ N58](#))

First published April 2020

Revised version published September 2023

Personalized Medical Devices – Production Verification & Validation ([IMDRF/PMD WG/ N74](#))

Published April 2023



Personalised Medical Devices Working Group

Recent activities

At the IMDRF MC meeting in Seattle (Sept 2024), the PMD WG presented survey results on the adoption / implementation of N49 PMD Definitions and N58 PMD Regulatory pathways in various jurisdictions



Survey results:

Document	Adoption / Implementation Status
N49 PMD definitions	4 fully adopted and 7 partially adopted across jurisdictions Difference between custom made and patient matched definitions not always clear
N58 PMD regulatory pathways	5 fully adopted and 6 partially adopted custom made medical device guidance across jurisdictions; Some have restricted supply to 5 or less devices per year
	7 fully adopted and 2 partially adopted patient matched medical device guidance across jurisdictions; understanding of specified design envelope not consistent
	6 fully adopted and 4 partially adopted adaptable medical device guidance across jurisdictions; treated the same as mass-produced devices
	0 fully adopted and 3 partially adopted medical device production system guidance across jurisdictions; is a novel concept and not well understood; healthcare system challenges; some exemptions for point of care manufacturing of medical devices



Personalised Medical Devices Working Group – current focus

- The WG proposed to develop a general webinar about N49 and N58 documents including Questions and Answers. This would inform future training material options including the target audiences.
- The WG also proposed to explore case studies regarding Medical Device Production Systems
- Competing priorities have impacted the delivery of the webinar but is still under active consideration