IMDRF PMD WG Comment Form

Date: 23 July 2019	Document: **PMD WG/(PD2): Personalized Medical Devices – Regulatory Pathways**

Name/Organization	Document Section	Comments	Proposed Change	WG Resolution
Medical Technology Association of Australia (MTAA)	4.0 Definitions	From the definitions for custom-made and patient-matched medical devices it appears that the main differences between these two categories are: 1) Responsibility: authorised health professional for custom-made vs manufacturer for patient-matched 2) Validation and reproducibility: possible/required for patient-matched devices only 3) Availability of an alternative device on the market: if an alternative device is available there is no justification for a custom-made device 4) Written request from an authorised health professional: required for custom-made devices only Are there device categories that can be either custom-made or patient-matched depending on who takes responsibility for them? How significant must the difference be between a device already available on the market and a custom-made device?	The guidance should include specific examples to better distinguish between custom-made and patient-matched devices. For example: • dental appliances such as crowns, bridges and dentures • prosthetic or glass eyes • orthopaedic or pedorthic footwear • prosthetic limbs • prescription glasses • 3D printed implants replacing bones/ joint replacements in human body. The guidance should include examples of devices can be custom-made or patient-matched depending on how they are managed, with an emphasis that all requirements for each definition are met. The guidance should include examples of “significant differences” that might justify having a custom-made device.	

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	7.0 Patient-matched Medical Devices	The labelling requirements for patient-matched medical devices should align with labelling requirements for medical devices in general.	Implantable patient-matched medical devices should be required to have a patient implant card (PIC) and a patient information leaflet (PIL) where mandated by the regulations.	
	Appendix 1 Considerations for personalised devices produced using additive manufacturing	MTAA is aware that FDA regulates certain materials as medical devices. However, we recommend that materials for personalised devices using additive manufacturing should be controlled as any other materials and components used in medical devices. Currently, health institutions using MDPS produce personalised devices in all risk categories, from low risk dental restorations to high risk implantable bone replacements.	Materials and components should not be regulated as stand-alone medical devices because on their own they do not fulfil any medical purpose. Compliance with applicable essential principles of safety and performance is managed via the manufacturer's QMS. Since the responsibility for the medical device rests with the manufacturer operating an MDPS, health institutions operating an MDPS should be regulated as any other medical device manufacturer, except for low risk devices such as dental restorations.	
	Appendix 2 Considerations for point-of-care production of personalised medical devices	Health professionals prescribing a custom-made device are responsible for specifying its design characteristics or construction. If they are also the manufacturer or sponsor of the medical device, then they must also meet the applicable responsibilities of a manufacturer/ sponsor as defined in	Revise sentence in paragraph 4 on page 13 as follows: "Health institutions designing and/or manufacturing personalised medical devices at the point-of-care undertake regulated activities of a medical device manufacturer and <u>should comply</u> [*instead of "should consider"*] with the	

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		section 6.0 Custom-made Medical Devices of the IMDRF draft guidance. Similarly, health institutions manufacturing patient-matched medical devices and adaptable medical devices at the point-of-care should be regulated in the same way as a medical device manufacturer and meet the requirements defined in sections 7.0 Patient-matched Medical Devices and 8.0 Adaptable Medical Devices respectively of the IMDRF guidance.	following: (a) […] (g)”	