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AMA submission – TGA proposed regulatory changes related to personalised and 3D printed medical devices

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The AMA supports the proposals outlined in the TGA's consultation paper of November 2017 for changing the regulatory framework underpinning personalised and 3D medical devices.

The AMA considers these are sensible and reasonable changes which recognise the increasing use of 3D printing for high risk implantable medical devices, and which are required to mitigate the risks to patients arising from these and other personalised devices.

In particular the AMA supports the new definition of 'patient specific' medical devices which would capture 3D printed medical devices and allow them to be regulated under the TGA's existing regulatory framework, commensurate with their risk classification level. This will facilitate ARTG listing and patient access to safe and quality products providing optimal outcomes.

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