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18 February 2019

Device Reforms
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Via e-mail: devicereforms@tga.gov.au

Dear Sir / Madam

Re: Consultation: Potential reclassification of active medical devices for diagnosis and patient therapy

Becton Dickinson (BD) has read with great interest the above consultation document, as published by the Therapeutic Goods Administration (TGA) on 9 January 2019.

Answers to the questions posed in the document are provided below.

Questions

- **What impacts—including any that are unintended—do you anticipate the reclassification may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?**

  While BD agrees alignment of the Australian Classification Rules with those of the European Union (EU) will be a positive future step, unintended impacts can be minimised if the TGA ensures:

  - Such alignment does not occur in Australia until the new EU Medical Device Regulations are fully implemented; and
  - The interpretation of the new Australian Classification Rule aligns with that used by the EU Notified Bodies (NBs) once the new EU Medical Device Regulations are fully implemented

(i.e. the same types of products are impacted by the new Australian Classification Rule as will be impacted by Rule 22 of the EU Medical Devices Regulations).

- **Are there any further issues and questions we should consider when implementing this change (i.e. areas that need to be clarified in our guidance)?**

  As commented above, BD encourages the TGA to minimise unintended impacts through misaligned timings and interpretation of the new Australian Classification Rule.

- **Other medical devices covered by the EU MD Regulation Rule 22 (in addition to AEDs and closed loop systems) may include:**
  – external pacemakers
  – continuous positive airway pressure (CPAP) devices
  – intravascular heating/cooling system control units
  – hyperthermia systems, temperature mapping units
  – intraperitoneal-circulation hypothermia system control units
  – mechanical bloodstream indicator injectors.
  We seek your feedback whether reclassification of any or all of these devices in Australia to Class III is appropriate.

  Input to this question should be delayed until there is greater clarity around how the EU NBs will interpret Rule 22 of the EU Medical Devices Regulations. The Australian classification of the devices listed above should be the same as that used by the EU Notified Bodies (NBs) once the new EU Medical Device Regulations are fully implemented.

- **Are there any other groups of devices that we have not considered which might fall within the scope of this proposed change?**

  Input to this question should be delayed until there is greater clarity around how the EU NBs will interpret Rule 22 of the EU Medical Devices Regulations.

- **Do you have any comments regarding the transitional arrangements proposed in this paper?**

  As commented above, implementation should not occur in Australia until the new EU Medical Device Regulations are fully implemented.

Becton Dickinson looks forward to continued consultations as the TGA develops their thinking around medical device cybersecurity.

Yours sincerely,