13 June 2018

Ms Nor Jalilah Md Yusop
Department of Standards Malaysia
Century Square,
Level 1 & 2, Block 2300
Jalan Usahawan
63000 Cyberjaya, Selangor

Subject: Response from the Asia Pacific Medical Technology Association (APACMed) to the Second Public Comment on the Draft Malaysian Standard (MS): Halal Medical Device – General Requirements (16/04/2018 – 15/06/2018)

Dear Ms Nor Jalilah Md Yusop:

We are writing further to our letters dated 27 September 2017, 31 January 2018 and 12 February 2018 to the Minister of Health on the above matter and express our appreciation for the opportunity to provide supplementary views on the same. The Asia Pacific Medical Technology Association (APACMed) represents medical device manufacturers (multinational corporations as well as small and medium enterprises) across the region, together with several national industry associations. We are fully committed to ensuring patient access to safe, high-quality medical devices.

Medical devices, as defined under the Medical Device Act 2012 (Act 737) include a vast range of products, from simple high-volume consumables such as tongue depressors or syringes; to life saving implantable devices such as pacemakers, to capital equipment such as CT and MRI imaging systems. There are more than 500,000 medical technologies that, unlike most pharmaceuticals, rely on complex global manufacturing and distribution supply chains. Malaysia is an important part of this worldwide network. Note that an overwhelming majority (90%) of the medical devices produced in your country - worth over RM 17 billion in 2017 - are intended for export.

We are deeply concerned that any disruption to the regulatory environment for the medical device industry in Malaysia – caused by the draft standard – will negatively impact this global supply chain, increase the costs of doing business in the country, and adversely affect patients’ access to innovative medical technology not just in Malaysia but in many other parts of the world.

We are also concerned that the implications of this standard have not been adequately reviewed by practicing clinicians, surgeons and other healthcare professionals in Malaysia.

In view thereof, the APACMed very respectfully recommends that the Malaysian Government suspend consideration of the draft standard pending a comprehensive and multi-stakeholder review of its end-to-end impact on the entire medical device value chain, the costs of doing business in Malaysia as well as its effects on patient’s access to innovative medical technology.
We remain fully committed to collaborating with the people and government of Malaysia to advance our common objectives of increasing patient access to quality, affordable medical technology, while ensuring a robust and sustainable ecosystem that encourages investment and innovation.

Sincerely,

Fredrik Nyberg
Chief Executive Officer
Asia Pacific Medical Technology Association (APACMed)

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About APACMed

Founded in 2014, the Asia Pacific Medical Technology Association (APACMed, 亚太医疗技术协会) is the first and only regional association to provide a unified voice for the medical technology industry in Asia Pacific. APACMed works proactively with bilateral, regional and local government bodies to shape policies, demonstrate the value of innovation and promote regulatory harmonisation. APACMed engages with medical device associations and companies in Asia Pacific to jointly advance regional issues, code of ethics and share best practices.

APACMed Corporate Members