MS. KONNY SAGALA
WTO TBT Notification and Enquiry Point of Indonesia
Directorate of Implementation System for Standards and Conformity Assessment
National Standardization Agency of the Republic of Indonesia (BSN)
BPPT Building I, 12th floor, Jln. M. H. Thamrin No. 8, Jakarta Pusat, DKI
Jakarta 10340, Indonesia

Singapore, 2 September 2021

Dear Ms. Konny Sagala,

RE: APACMed Recommendation Letter on WTO Regular TBT Notification IDN/134 (Indonesia)

The Asia Pacific Medical Technology Association (APACMed) represents over 250 members from across the Asia Pacific region. Together, we are committed to working with governments and other stakeholders to facilitate patient access to innovative and life-saving medical technologies, supporting strong and thriving healthcare systems across the region, and promoting a robust and sustainable regional ecosystem that encourages investment, trade and innovation.

APACMed is pleased to submit comments in response to the Draft Decree of The Ministry of Religious Affairs of Indonesia regarding Types of Products and Consumer Goods Products Mandatory to be Halal Certified notified to WTO on July 2, 2021.

The draft stipulates the scope of products subject to mandatory halal certification, including a very large number of medical devices. APACMed believes that the scope of coverage in the draft is overly broad. While it is listed as covering 17 categories, with 68 sub-categories, it covers nearly 3,000 types of products based on Indonesian Ministry of Health data.

Table 1: Inputs and Justifications on the Draft Decree

Point	Input	Justification
Point - 9 related to Medical Device	To be revised as "Invasive Medical Device that are made from animal products/ derivative in/as their main raw materials"	- To align with previous Government Regulation number 39, 2021 article 138, where consumer goods included in the scope are products that are made from animal and derivatives only (Medical Device fall under this category). Most of Medical Devices are not available OTC and are being used by HCPs. - To align with Medical Device International Regulation (GHTF/AMDD Classification on rule 14) related to Medical Device that are made from animal and derivative. *Refer to proposal 1&2*
9.1 to 9.17 Details list of Medical Device categories	To be revised as "List of Medical Device categories to be aligned with Ministry of Health regulation"	Suggest removing all Medical Devices categories in order to make it more general and accommodative if there are changes/additions on types/categories of Medical Devices as per MoH regulation update. *Refer to proposal 3*

Table 2: Examples of products falling under the criteria to be exempted

No	Product Criteria	Examples
1	Medical Devices that have no contact with the human body	Non-Invasive Medical Devices and In Vitro Diagnostic Medical Devices
2	Medical Devices which have no animal products/derivatives as a composition in the final products.	Active Medical Devices (radiation and non-radiation electromedical machines), accessories and machine spare parts.
3	Medical Devices which have no animal materials/ derivatives in their main raw materials.	Surgical instruments made of metal, contact lenses made of synthetic materials, surgical equipment derived from plants and synthetics such as surgical sutures from synthetic materials, hemostat agents, laparoscopic devices, Cardiology equipment such as cardiac catheters, ECG sensors, patient tubing for breathing

Since Indonesia will be the first country implementing mandatory halal certification for medical device, we believe the role and expertise of Ministry of Health is paramount. APACMed would like to submit our recommendations to the Ministry of Health for your kind consideration -

Proposal 1: APACMed requests to align the scope of Medical Devices that is mandatory for Halal certification, to previously released regulation (Government Regulation No.39, 2021) and help to streamline the overall approach in further alignment with GHTF/AMDD Classification on rule 14 related to definition on Medical Device that are made from animal and derivative which limited to their main raw material only as pointed out in Table 1.

Proposal 2: APACMed requests for products in Table 2 to be exempted from Mandatory Halal Certification scope. This exemption will pave the way for a healthier Indonesia wherein significant unintended consequences can be prevented. For example, the time and expense to achieve halal certification will act as a barrier to timely introduction of products into the Indonesian market by medical device manufacturers. Moreover, the flow of imported medical devices into Indonesia could be significantly impeded and impact patients' access to cutting edge medical and clinical solutions and quality healthcare services.

Proposal 3: In addition to the above, APACMed would also like to propose that the role of Ministry of Health in this regulation will also cover responsibilities including but not limited to -

1) Reviewing the list of product categories that are obliged to receive halal certification.
2) Determining the specific type of products that must receive halal certification, considering the characteristics of each type of medical device, including (but not limited to) generating a positive list of medical devices to be covered; and
3) Providing guidelines for the implementation of halal certification, including the labeling requirements, criteria of products, etc.

On behalf of APACMed's members, I would like to thank you for providing us with this opportunity to share our comments and recommendations on this important subject. As a trade association, we always strive to seek a common ground between our members and the policy makers/regulators to uphold public safety for medical devices in optimal regulated environment and remain committed to ensuring timely patient access to safe and effective medical devices of the highest ethical standards.

We hope our recommendations are considered favorably and welcome an opportunity for further discussions and deliberations.

I hereby include here the contact details of Praveen for your response: gpkumar@apacmed.org

Yours Sincerely,

Best regards,

Harjit Gill (Ms)
Chief Executive Officer
Asia Pacific Medical Technology Association (APACMed)

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Copy:

1. **Praveen Kumar – Manager, Regulatory Affairs, APACMed**
2. **Anirudh Sen – Director, Regulatory Affairs, APACMed**

About APACMed
Founded in 2014, the Asia Pacific Medical Technology Association (APACMed) is the first and only regional association to provide a unified voice for the medical technology industry in Asia Pacific. As a non-profit organization, APACMed works proactively with bilateral, regional and local government bodies to shape policies, demonstrate the value of innovation and promote regulatory harmonization. APACMed engages with medical device associations and companies in Asia Pacific to jointly advance regional issues, code of ethics and share best practices.

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