



No. 2021-12

The Permanent Mission of the Republic of the Philippines to ASEAN in Jakarta presents its compliments to the ASEAN Secretariat and has the honor to deposit with the Secretary-General of ASEAN, the attached Philippines' Instrument of Ratification of the ASEAN Agreement on Medical Device Directive.

The Permanent Mission of the Republic of the Philippines to ASEAN in Jakarta avails itself of this opportunity to renew to the ASEAN Secretariat the assurances of its highest consideration.

Jakarta, 26 February 2021

The Secretariat
Association of Southeast Asian Nations



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MALACAÑANG
MANILA

INSTRUMENT OF RATIFICATION

TO WHOM THESE PRESENTS SHALL COME, GREETINGS:

KNOW YE, that whereas, the *Association of Southeast Asian Nations (ASEAN) Agreement on Medical Device Directive* ("Agreement") was signed by the ASEAN Economic Ministers on 21 November 2014 in Bangkok, Thailand;

WHEREAS, the Agreement recalls the ASEAN Framework Agreement and the ASEAN Sectoral Integration Protocol for Healthcare signed on 29 November 2004 in Vientiane, Lao PDR;

WHEREAS, the Agreement aims to harmonize regulations on technical requirements and registration systems of medical devices across the ASEAN Member Economies;

WHEREAS, the Agreement is expected to benefit manufacturers of medical devices in the Philippines as it would ease the processing time for registration of medical devices using the Common Submission Dossier Template;

WHEREAS, the Agreement facilitates better collaboration between the ASEAN Member Economies by enabling the sharing of information among them, as well as by providing a better understanding of the regulatory processes of each Member State through the Post-Marketing Alert System that will be established;

WHEREAS, Article 22 of the Agreement provides that it shall be subject to ratification and/or acceptance by Member States in accordance with their internal domestic requirements, and shall be in force only among the Member States that have ratified and/or accepted it; and

WHEREAS, in preparation for the ratification and transposition of the Agreement into national legislation, the Food and Drug Administration issued Administrative Order No. 2018-002, entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements";


NOW, THEREFORE, be it known that I, **RODRIGO ROA DUTERTE**, President of the Republic of the Philippines, after having seen and considered the *ASEAN Agreement on Medical Device Directive*, do hereby ratify and confirm the same and each and every article and clause thereof.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the seal of the Republic of the Philippines to be affixed.

GIVEN under my hand at the City of Manila, this 18th day of November in the year of Our Lord Two Thousand and Twenty.



By the President:



SALVADOR C. MEDIALDEA
Executive Secretary

