Certificate of Technical Cooperation Programme on Exchange of Medical Device Quality Management System Regulations and ISO 13485 Audit Reports (Version 3)

This is to certify that:

EU MDR/IVDR Notified Body Partner: DEKRA Certification B.V.
Address: Meander 1051, 6825 MJ Arnhem, The Netherlands
Notified Body 0344
Valid Until: December 31, 2025

According to Ministry of Health and Welfare Notice No. 1111108228 dated 7 January 2023, the above-mentioned EU Notified Body Partner has been assessed and found to be in compliant with the third generation of Technical Cooperation Programme on Exchange of Medical Device Quality Management System Regulation and ISO 13485 Audit Reports (Version 3).

Signed by

TFDA Authorized Auditing Organization

Deputy Director, MIRDC

CEO, ETC

President, PIDC

Director, OMDE, CMS/ITRI

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