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To:
Sanctuary Health Sdn Bhd
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31200 Chemor, Perak,
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CE
European Authorised Representative
For Medical Devices

Auth Rep Certificate

No. **ARMDD11931L221123NI**
(Valid until: **30 January 2024**)

This is to certify that **Wellkang Ltd (SRN in EUDAMED: XI-AR-000001836,** under **Competent Authority: XI-CA-071,** MHRA (Northern Ireland)) has formally accepted the renewed appointment as the European Authorised Representative (EC Rep) for manufacturer (**SRN** in EUDAMED: **MY-MF-000002197**) **Sanctuary Health Sdn Bhd.** located at **No. 16 Persiaran Perindustrian Kanthan 1, Kawasan Perindustrian Kanthan, 31200 Chemor, Perak, Malaysia**, per MDD Directive 93/42/EEC as amended, and/or, IVDD Directive 98/79/EC, and/or, MDR-Regulation (EU) 2017/745 , and/or IVDR-Regulation (EU) 2017/746, where applicable.

This representation including the information on the products represented is subject to the terms and conditions stated in the Authorised Representative Agreement signed between our two companies, and has been published online for verification by third parties at - **http://www.cemark.info/mdd/SanctuaryHealth.html**

You may start to use Wellkang Ltd's name/address as the EC Rep for the CE-marked products represented by Wellkang. Please be advised that **Wellkang is NOT involved in the Design, Manufacture and/or Marketing, Distribution, Sales, Supply, Installation of your products**, when you start to sell the product(s) on the EEA Market, please make sure to properly affix the CE Marking on the product(s), the labelling, packaging, and/or other accompanying materials according to the related EU directives. Per Article R4 of EU COUNCIL DECISION No 768/2008/EC, **EU Importers MUST indicate their name and address on the product or its packaging & IFU.** The Importers shall also ensure that the product is accompanied by instructions and safety information in **a language which can be easily understood by consumers and other end-users**, in the official language(s) of the EEA member state(s) in which the products are placed on the market; **You MUST provide Wellkang with the true, accurate and most-updated Technical Documentation** (including IFU), per EU Decision No. 768/2008/EC, prior to any shipment of your products, which carry the name of Wellkang Ltd as the Authorised Representative, to the EEA market. Please inform us immediately whenever there is a change about either the above-mentioned product(s) or your company details. So we can update your CE Marking documentation promptly and properly.

Derry/NI, 23rd Nov 2022.

For and on behalf of
WELLKANG LIMITED

Authorized Signature(s)

Signature of Responsible
Wellkang Ltd