Our Case Ref.:

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Your Ref./Contact Persons:

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To:

Sanctuary Health Sdn Bhd No. 16 Persiaran Perindustrian Kanthan 1 Kawasan Perindustrian Kanthan 31200 Chemor, Perak, Malaysia European Authorised Representative For Medical Devices

## **Auth Rep Certificate**

No. **ARMDD11931H171121LN** (Valid until: **30 January 2019**)

This is to certify that Wellkang Ltd has formally accepted the renewed appointment as the European Authorised Representative (EC Rep) for manufacturer- Sanctuary Health Sdn Bhd. located at No. 16 Persiaran Perindustrian Kanthan 1, Kawasan Perindustrian Kanthan, 31200 Chemor, Perak, Malaysia, per the EU MDD Directive 93/42/EEC amended by Directive 2007/47/EC. The manufacturer may use Wellkang's name & address as the EC Rep for the CE-marked products represented by Wellkang. The examples of use of Wellkang's name/address can be found at:

http://www.ce-marking.com/ec-rep.html

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

When you start to place the above-mentioned 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 and guidelines which have already been provided to you by us.

Please be advised that Wellkang is NOT involved in the Design, Manufacture and/or Marketing, Distribution, Sales, Supply, Installation of your products, it is therefore your responsibility to provide the Instruction For Use (IFU), if applicable and required by the legislation of the EEA member state(s), in the official language(s) of the EEA member state(s) in which the products are placed on the market. You need to provide us with the true, accurate and most updated Technical Documentation (Technical Files) 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.

London/UK, 21st Nov 2017.

For and on behalf of WELLKANG LIMITED

Signature of Responsible Wellkang Ltd