

Sancare Health Co., Ltd

DECLARATION OF CONFORMITY

We, Sancare Health Co., Ltd. (Manufacturer's Name)

No.38, Ln. 221, Renhua Rd., Dali Dist., Taichung City 412, Taiwan (address)

Declare under our sole responsibility that the product:

- Pulsatile Nasal Irrigator (Class IIa)
- Pulsatile Ear Irrigator (Class IIa)
 - pump system
 - water container and its lid
 - mushroom valve
 - spiral diaphragm
 - motor
 - footswitch
 - panel overlay
 - lid of storage box
 - electronic system
 - replacement ear tips

To which this declaration relates is in conformity with the following standard(s) or other normative documents(s):

EN ISO 15223-1:2016, EN 1041:2008, EN 60601-1:2006, EN 60601-1-2:2015,
EN 60601-1-6:2010, EN 60601-1-11:2010, EN ISO 14971:2012, EN ISO 10993-1:2009,
EN ISO 10993-5:2009, EN ISO 10993-10:2009, EN ISO 13485:2016, EN 62304:2006,
and EN 62366:2008

(title and/or number and date of issue of the standard(s) or other normative document(s))

(if applicable)

following the provision of Directive:

93/42/EEC and its amendment 2007/47/EC Annex II excluding sec.4

EC Certificate: F116/07016

UK & EU Authorized Representative:

Albert Waeschle Ltd. (name)

11 Balena Close Poole, Dorset, UK BH17 7DB (UK address)

20 Harcourt Street, Dublin 2, Ireland (EU address)

Notified Body (NB):

SGS (0598), SGS Fimko Ltd., Särkiniementie 3, FI-00211 Helsinki, Finland

Taiwan, 2021/07/22

(place and date of issue)

Jimmy Tseng

(Name and signature of equivalent marking of authorized person)

