

# 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)

