

S003 (EN ISO/IEC 17065)

EC Certificate Full Quality Assurance System FI16/07016

The management system of

Sancare Health Co., Ltd.

No.38, Ln.221, Renhua Rd., Dali Dist., Taichung City 412, Taiwan R.O.C.

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices, Annex II (excluding section 4)

For the following products

Pulsatile nasal irrigator
 Pulsatile ear irrigator

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 07 May 2020 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 23 September 2016
This certification is based on decision: FI20/07018P0

Authorised by

of Value

Seppo Vahasalo Notified Body Manager

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Attachment 1 to SGS Fimko Ltd. EC certificate FI16/07016 Issue 2

| Manufacturer | Sancare Health Co., Ltd. | |
|---|--|--|
| Address | No.38, Ln.221, Renhua Rd., Dali Dist., Taichung City 412, Taiwan R.O.C. | |
| Activity and Medical Device Product Category | 93/42/EEC Annex II (excluding Section 4) 1. Pulsatile nasal irrigator 2. Pulsatile ear irrigator | |

List of medical devices and the corresponding type/model markings with product trademarks/marketing names covered by this certificate:

| Medical Device | Class | Trademark(s) and Model(s)/type(s) | |
|---------------------------|-------|-----------------------------------|--|
| Pulsatile nasal irrigator | lla | SH95, SH950, SH951, SH953, SH954 | |
| Pulsatile ear irrigator | lla | OtoJet 101, Projet 101 | |