

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

1. Pulsatile nasal irrigator
2. 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

Seppo Vahasalo
Notified Body Manager

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Attachment 1 to SGS Fimko Ltd. EC certificate F116/07016 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	Ila	SH95, SH950, SH951, SH953, SH954
Pulsatile ear irrigator	Ila	OtoJet 101, Projet 101