EC Certificate Full Quality Assurance System FI17/07012

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The management system of

Icare Finland Oy

Äyritie 22
01510 Vantaa
FINLAND

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

Tonometers and accessories for the area of ophthalmology, and lung function testing system for the area of pulmonology

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 8 December 2017 until 8 December 2022
and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 8 September 2020
Issue 2. Certified since 3 October 2017
This certification is based on decision: FI17/07012P1

Authorised by

Tom Törn, Certification Director
SGS Fimko Ltd., Notified Body 0598

Attachment 1 to SGS Fimko Ltd. EC certificate FI17/07012, issue 2

Manufacturer	Icare Finland Oy
Address	Äyritie 22 01510 Vantaa Finland
Activity and Product Category	93/42/EEC Annex II (excluding Section 4) Tonometers and accessories for the area of ophthalmology, and lung function testing system for the area of pulmonology

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

Product Name	Class	Model/type nr. and Trademark(s)
Tonometer	IIa	TA01i
Tonometer	IIa	TA02
Tonometer	IIa	TA03
Tonometer	IIa	TA011
Tonometer	IIa	TA022
Tonometer	IIa	TA031
Bioimpedance recorder for lung function diagnosis	IIa	IPREC01 / Ventica

Authorised by

Seppo Vahasalo, Notified Body Manager
SGS Fimko Ltd., Notified Body 0598

Date issued/revised: 11 September 2018, attachment issue 3