

EC Certificate Full Quality Assurance System FI17/07012

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 24 November 2020 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 3 October 2017
This certification is based on decision: FI20/07068P0

Authorised by

Seppo Vahasalo Notified Body Manager

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## Attachment 1 to SGS Fimko Ltd. EC certificate FI17/07012 Issue 4

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

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)
Tonometer	lla	TA01i
Tonometer	lla	TA011
Tonometer	lla	TA022
Tonometer	lla	TA023
Tonometer	lla	TA031
Bioimpedance recorder for lung function diagnosis	lla	IPREC01 / Ventica