

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

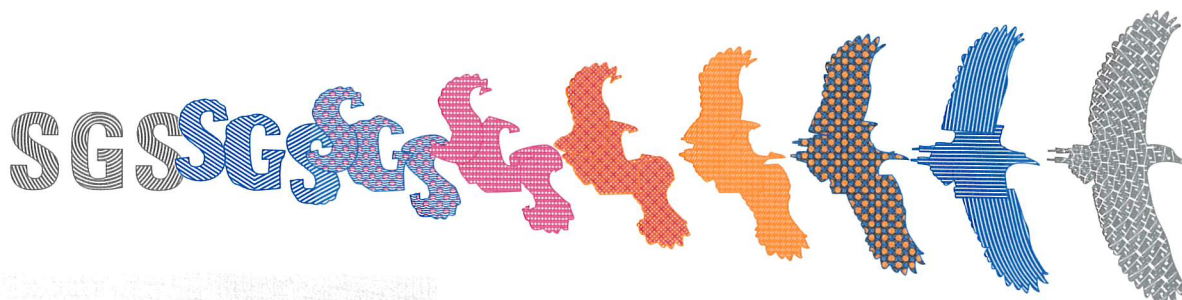
Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 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

<b>Manufacturer</b>	Icare Finland Oy
<b>Address</b>	Äyritie 22 01510 Vantaa Finland
<b>Activity and Product Category</b>	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:

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

Authorised by



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

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