

Identification of the Legal Manufacturer:	 Icare Finland Oy Äyritie 22 FI-01510 Vantaa Finland
This Declaration of Conformity is issued under the sole responsibility of the Legal Manufacturer.	
Identification of the device(s) concerned:	TA011 (iCare IC100)
Risk Classification	Ila; Annex IX, Rule 10
We hereby declare that the above-mentioned devices comply with the European Medical Devices Directive 93/42/EEC as modified by 2007/47/EC, RoHS 2 Directive 2011/65/EU.	
Relevant Harmonized Standards	EN 60601-1:2006 + A12:2014 EN 60601-1-2:2015 IEC 60601-1-6:2010 + A1:2013 IEC 62304:2006 + A1:2015 EN 62366:2008 EN 15004-1:2009 EN 15223-1:2016, EN 1040:2008 +A1:2013
GMDN code:	16809
Notified Body name and identification number:	SGS Fimko Ltd. 0598
Applicable CE Certificate(s):	EC Quality System Certificate No. FI17/07012, issued by the Notified Body, in accordance with Annex II (excluding Section 4) of this Directive.
Identification of the person authorized to sign on behalf of Legal Manufacturer:	Name: Jouni Toijala Signature:  Title: CEO Place of Issue: Vantaa Date: 02.03.2021

REVISION HISTORY

Rev.	Date	What changed?	Why did it change?	Author
1.0	01.04.2015	DoC published in a new template.	Template.	Matti Tulikoura
2.0	03.10.2017	New Notified Body SGS Finland Oy.	NB, their contact information and number.	Matti Tulikoura
3.0	01.01.2018	EN980:2008 superseded with EN 15223-1:2016 standard GMDN code added RoHS directive added	EN980:2008 was superseded with a new standard.	Matti Tulikoura
4.0	17.01.2019	Formatting changes, header update, CE certificate number corrected, added trademark to device identification, updated EMC to 4 th edition EN 60601-1-2:2015	Formatting changes, request to add trademark information for registration to Russia, CB testing	Hannes Hyvönen
5.0	12.5.2020	-NB address removed -removed trademark symbol -removed EN 14971:20212 as process standard -added amendments to IEC 62304 and IEC 60601-1-6	-NB address not mandatory requirement -trademark symbol not required -EN 14971 embedded in Icare risk management process -include amendment A1:2015 to IEC 62304 and A1:2013 to IEC 60601-1-6	Hannes Hyvönen
6.0	04.06.2020	-Updated signee	-CEO change	Hannes Hyvönen
7.0	02.03.2021	-redated	-reissued for notarization	Hannes Hyvönen