


Identification of the Legal Manufacturer:	 <p>Icare Finland Oy Äyritie 22 FI-01510 Vantaa Finland</p>
This Declaration of Conformity is issued under the sole responsibility of the Legal Manufacturer.	
Identification of the device(s) concerned:	TA031 (iCare IC200)
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 and Radio Equipment Directive 2014/53/EU (RED).	
Relevant Harmonized Standards	<p>EN 60601-1:2006 + A1:2013 EN 60601-1-2:2015 IEC 62366:2007 + A1:2014 EN 62304:2006 + A1:2015 EN 15004-1:2009 EN 15233-1:2016</p>
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:	<p>Name: Jouni Toijala</p> <p>Signature: </p> <p>Title: CEO</p> <p>Place of Issue: Vantaa</p> <p>Date: 02.03.2021</p>

REVISION HISTORY

Rev.	Date	What changed?	Why did it change?	Author
1.0	26.6.2018	Doc Published	New document	Krista Ingström
2.0	4.1.2019	Formatting changes, header update, added radio equipment directive (RED) information, added trademark to device identification	Formatting changes, request to add trademark information for registration to Russia	Hannes Hyvönen
3.0	12.5.2020	-NB address removed -removed trademark symbol -removed reference to QMS standard 13485 -added EN 15223-1:2016	-NB address not mandatory requirement -trademark symbol not required -embedded in Icare quality management system -standard reference added	Hannes Hyvönen
4.0	04.06.2020	-Updated signee -Usability standard reference corrected from EN 62366-1 to IEC 62366:2007 + A1:2014	-CEO change -Corrected standard reference	Hannes Hyvönen
5.0	02.03.2021	-redated	-reissued for notarization	Hannes Hyvönen