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DECLARATION OF CONFORMITY

Device: TA011
Author: Matti Tulikoura
Effective date: 15.06.2018
Revision: 3.0

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
Risk Classification:	II a; 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 and RoHS 2 Directive 2011/65/EU.	
Relevant Harmonized Standards	EN 60601-1: 2006 + A12:2014, EN 60601-1-2:2007 EN 60601-1-6:2010, EN 62304:2006 EN 62366:2008, EN 15004-1:2009, EN 15223-1:2016, EN 1040:2008 +A1:2013, EN 14971:2012
GMDN code:	16809
Name and address of Notified Body:	SGS Finland Oy Särkiniementie 3 00211 Helsinki Finland
Applicable CE Certificate(s):	EC Quality System Certificate No. FI17/07012, issued by the SGS Finland Oy Notified Body Number 0598, in accordance with Annex II (excluding Section 4) of this Directive.
Identification of the person authorized to sign on behalf of Legal Manufacturer:	Name: Heli Valtanen Signature: Title: QA Director Place of Issue: Vantaa Date: 15.06.2018

Digitally signed by Bolea Petru
Date: 2021.07.01 12:05:50 EEST
Reason: MoldSign Signature
Location: Moldova

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3.0	01.01.2018	EN980:2008 superseded with EN 15223-1:2016 standard GMDN code added RoHS directive added	EN980:2008 was superseded with a new standard.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	15.06.2018	Signed by H. Valtanen	CE certificate number added, signee changed	Heli Valtanen