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DECLARATION OF CONFORMITY

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:	TP01
Risk Classification:	I; Annex IX, Rule 5
We hereby declare that the above-mentioned devices comply with the European Medical Devices Directive 93/42/EEC and RoHS 2 Directive 2011/65/EU.	
Relevant Harmonized Standards	EN ISO 10993-1:2009 EN ISO 10993-5:2009 EN ISO 15223-1:2016 EN 1041:2008 +A1:2013
GMDN code	62406
Notified Body name and identification number:	-
Applicable CE Certificate(s):	-
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

SOCIETATEA COMERCIALA KEMBLI MED S.R.L. BRASOV - ROMANIA

CONFORM CU ORIGINALUL

Digitally signed by Ceaicovschi Tudor
Date: 2024.07.25 09:46:21 EEST
Reason: MoldSign Signature
Location: Moldova

REVISION HISTORY

Rev.	Date	What changed?	Why did it change?	Author
1.0	15.01.2015	DoC published		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3.0	01.01.2018	EN980:2008 superseded with EN 15223-1:2016 standard added RoHS 2 Directive	EN980:2008 was superseded with a new standard	Matti Tulikoura
4.0	10.06.2020	Updated signee	CEO change	Hannes Hyvönen
5.0	02.03.2021	Corrected GMDN code from 15238 to 62406	GMDN code correction	Hannes Hyvönen