

Declaration of Conformity

Manufacturer:	Bittium Biosignals Ltd. Pioneerinkatu 6 70800 Kuopio, Finland
Software:	
Product Name:	Cardiac Navigator
Product code:	700144
Firmware versions:	1.5.x
GMDN:	47699
Medical Device Classification:	Class IIa
Notified Body Name and Identification number:	Eurofins Expert Services Oy 0537
Conformity assessment route:	Annex II, Full Quality System Certificate Certificate no. VTT-C-12239-01-1030-629-17

We, Bittium Biosignals Ltd declare under our sole responsibility that the product above complies with the following:

Directives:	Directive 93/42/EEC
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The following standards have been applied	IEC 60601-1-6:2010+AMD1:2013 IEC 62304:2006/A1:2016 IEC 62366-1:2015 IEC 60601-2-47:2012
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<i>Signed behalf of:</i>	Bittium Biosignals Ltd
<i>The Signatory's title and name:</i>	Senior Vice President, Arto Pietilä
<i>Place:</i>	Oulu
<i>Date:</i>	<i>July 5th 2021</i>
<i>Signature:</i>	