

QUALITY SYSTEM

EC-CERTIFICATE

Directive 93/42/EEC

Manufacturer: Bittium Biosignals Ltd
Pioneerinkatu 6
FI-70800 Kuopio
FINLAND

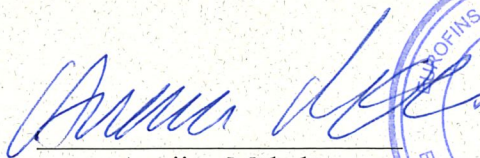
Coverage of Certificate: Design, manufacture and final inspection

Product category: Electromyographs, electrocardiographs,
electroencephalographs and diagnostic and
therapeutic devices for urinary incontinence,
telemedicine and health care management
systems

Valid until: 27th May 2024

The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 93/42/EEC as set out in Annex II Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex II in Directive 93/42/EEC. Products covered by the certificate are specified in the attachment(s).

Valid from: 20th April 2020


Anniina Mäkelä


Satu Rajala



Certificate no.
C-01-1030-730-20

Notified Body no. 0537:
Eurofins Expert Services
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

Attachment 1 to the Certificate number: C-01-1030-730-20

Manufacturer:	Bittium Biosignals Ltd Pioneerinkatu 6 FI-70800 Kuopio, Finland		
Activity and product category:	Design, manufacture and final inspection of electromyographs, electrocardiographs, electroencephalographs and diagnostic and therapeutic devices for urinary incontinence, telemedicine and health care management systems.		
Products:	The certificate covers the following products:		
	<i>Product</i>	<i>GMDN</i>	<i>Class</i>
	FemiScan Product Family (urinary incontinence treatment devices)		
	FemiScan Home Trainer	11474	Ila
	FemiScan Clinic Set	11474	Ila
	FemiScan Cover	11474	Ila
	ME6000 Product Family (portable telemetry and data logger systems)		
	Muscle Tester ME 6000	11474	Ila
	Analog Isolator ME3750-ISO	11474	Ila
	Wireless Bio Amplifier Product Family (wireless bioamplifiers)		
	WBA system	11474	Ila
	eMotion EMG	11474	Ila
	Faros Product Family (ECG recorders and transmitters)		
	Faros 90	11413	Ila
	Faros 180	38729	Ila
	Faros 360	38729	Ila
	Faros 14D	38729	Ila
	Faros 180L	38729	Ila
	Cardiac Navigator	47699	Ila
	NeurOne Product Family (EEG systems)		
	NeurOne system	11467	Ila

Eurofins Expert Services is Notified Body no. 0537 under Council Directive 93/42/EEC.

EUROFINS EXPERT SERVICES
 Medical Devices
 Kivimiehentie 4
 FI-02150 ESPOO, FINLAND

Business ID FI22975132

Attachment 1 to the Certificate number: C-01-1030-730-20

	KOTO Product Family (eHealth and mHealth solutions)		
	eHealth Monitor	31733	IIa
	WebMonitor	31733	IIa
	KOTO Mobile system	31733	IIa
	BrainStatus Product Family (EEG systems)		
	BrainStatus	35163	IIa
	BrainStatus C-Trend	35626	IIb
	Sleep Product Family		
	saPlot	44574	IIa
	APV20 recorder	33843	IIa
Date:	Valid from: 21 st May 2021		
	  		
	Aliina Nieminen Satu Rajala		

This Attachment 1 supersedes the previous Attachment 1 signed 20th April 2020.

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EUROFINS EXPERT SERVICES

Medical Devices

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FI-02150 ESPOO, FINLAND

v. 1.1 / 10.9.2018

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