

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: <table><tr><td><i>Product</i></td><td><i>GMDN</i></td><td><i>Class</i></td></tr><tr><td colspan="3">FemiScan Product Family (urinary incontinence treatment devices)</td></tr><tr><td>FemiScan Home Trainer</td><td>11474</td><td>IIa</td></tr><tr><td>FemiScan Clinic Set</td><td>11474</td><td>IIa</td></tr><tr><td>FemiScan Cover</td><td>11474</td><td>IIa</td></tr><tr><td colspan="3">ME6000 Product Family (portable telemetry and data logger systems)</td></tr><tr><td>Muscle Tester ME 6000</td><td>11474</td><td>IIa</td></tr><tr><td>Analog Isolator ME3750-ISO</td><td>11474</td><td>IIa</td></tr><tr><td colspan="3">Wireless Bio Amplifier Product Family (wireless bioamplifiers)</td></tr><tr><td>WBA system</td><td>11474</td><td>IIa</td></tr><tr><td>eMotion EMG</td><td>11474</td><td>IIa</td></tr><tr><td colspan="3">Faros Product Family (ECG recorders and transmitters)</td></tr><tr><td>Faros 90</td><td>11413</td><td>IIa</td></tr><tr><td>Faros 180</td><td>38729</td><td>IIa</td></tr><tr><td>Faros 360</td><td>38729</td><td>IIa</td></tr><tr><td>Faros 14D</td><td>38729</td><td>IIa</td></tr><tr><td>Cardiac Navigator</td><td>47699</td><td>IIa</td></tr><tr><td colspan="3">NeurOne Product Family (EEG systems)</td></tr><tr><td>NeurOne system</td><td>11467</td><td>IIa</td></tr></table>			<i>Product</i>	<i>GMDN</i>	<i>Class</i>	FemiScan Product Family (urinary incontinence treatment devices)			FemiScan Home Trainer	11474	IIa	FemiScan Clinic Set	11474	IIa	FemiScan Cover	11474	IIa	ME6000 Product Family (portable telemetry and data logger systems)			Muscle Tester ME 6000	11474	IIa	Analog Isolator ME3750-ISO	11474	IIa	Wireless Bio Amplifier Product Family (wireless bioamplifiers)			WBA system	11474	IIa	eMotion EMG	11474	IIa	Faros Product Family (ECG recorders and transmitters)			Faros 90	11413	IIa	Faros 180	38729	IIa	Faros 360	38729	IIa	Faros 14D	38729	IIa	Cardiac Navigator	47699	IIa	NeurOne Product Family (EEG systems)			NeurOne system	11467	IIa
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EUROFINS EXPERT SERVICES

Medical Devices
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

Business ID FI22975132

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	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
	Sleep Product Family		
	saPlot	44574	IIa
Date:	Valid from: 20 th April 2020		
	  		
	Anniina Mäkelä Satu Rajala		

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v. 1.1 / 10.9.2018

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