



Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Bittium Biosignals Ltd
Manufacturer address and contact details	Pioneerinkatu 6, 70800 Kuopio, Finland
Single Registration Number (SRN) (if available)	FI-MF-000013983

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	☒ See attached schedule
Notified body number (if applicable)	☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☒ See attached schedule

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☒ See attached schedule
End date of extended validity/transition period	☒ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements:

- ☐ Expired *before* 20 March 2023:
- ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
 - ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
 - ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

X Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- X** Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Unclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Quality Management System (QMS)**

Choose one applicable statement:

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☐ A QMS in accordance with Article 10(9) MDR is in place.
- X** A notified body has issued the attached certificate for the MDR-compliant QMS.



➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: Bittium Biosignals Ltd

Location & Date: Kuopio 2024-09-24 | 22:58 PDT

Signature, Print Name, Title:

DocuSigned by:

29793D4FA3104EC...

Laura Kauppinen, Sr. Vice President

Contact Details (at least email): laura.kauppinen@bittium.com

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) ³ (e.g., device name, family/group name device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Faros Product Family (ECG recorders and transmitters): Faros 180, Faros 180L, Faros 360, Faros 14D	C-01-1 030-730-20	27-May-2024	Eurofins Electric and Electronics Finland Oy (at the time, Eurofins Expert Services) 0537	Eurofins Electric and Electronics Finland Oy, 0537	31-Dec-2028	Mini UL
Cardiac Navigator	C-01-1 030-730-20	27-May-2024	Eurofins Electric and Electronics Finland Oy (at the time, Eurofins Expert Services) 0537	Eurofins Electric and Electronics Finland Oy, 0537	31-Dec-2028	Cardiac Navigator, 2.0

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

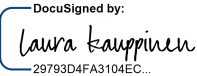
Certificate Of Completion

Envelope Id: E29FC027C178480C94D67E81AD847442	Status: Completed
Subject: Complete with DocuSign: Manufacturer's Declaration EU 2023607.docx	
Source Envelope:	
Document Pages: 5	Signatures: 1
Certificate Pages: 4	Initials: 0
AutoNav: Enabled	Envelope Originator:
Envelopeld Stamping: Enabled	Sanna Mattila
Time Zone: (UTC+02:00) Helsinki, Kyiv, Riga, Sofia, Tallinn, Vilnius	Ritaharjuntie 1
	OULU, Etelä-Karjala 90590
	sanna.mattila@bittium.com
	IP Address: 185.171.178.213

Record Tracking

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9/25/2024 8:52:37 AM	sanna.mattila@bittium.com	

Signer Events	Signature	Timestamp
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Laura Kauppinen	DocuSigned by:  29793D4FA3104EC...	Sent: 9/25/2024 8:54:53 AM
laura.kauppinen@bittium.com		Viewed: 9/25/2024 8:58:26 AM
SVP Medical Business		Signed: 9/25/2024 8:58:43 AM
Bittium Biosignals oy		
Security Level: Email, Account Authentication (None)	Signature Adoption: Pre-selected Style	
	Using IP Address: 185.171.178.213	

Electronic Record and Signature Disclosure:
Accepted: 9/25/2024 8:58:26 AM
ID: 454464db-090f-4acb-8fce-7014741813f9
Company Name: Bittium

In Person Signer Events	Signature	Timestamp
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Editor Delivery Events	Status	Timestamp
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Agent Delivery Events	Status	Timestamp
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Intermediary Delivery Events	Status	Timestamp
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Certified Delivery Events	Status	Timestamp
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Carbon Copy Events	Status	Timestamp
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Witness Events	Signature	Timestamp
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Notary Events	Signature	Timestamp
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Envelope Summary Events	Status	Timestamps
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Envelope Sent	Hashed/Encrypted	9/25/2024 8:54:53 AM
Certified Delivered	Security Checked	9/25/2024 8:58:26 AM
Signing Complete	Security Checked	9/25/2024 8:58:43 AM
Completed	Security Checked	9/25/2024 8:58:43 AM

Payment Events	Status	Timestamps
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Electronic Record and Signature Disclosure

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You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:

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To advise Bittium of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at ulla.kesti@bittium.com and in the body of such request you must state: your previous email address, your new email address.

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ii. send us an email to ulla.kesti@bittium.com and in the body of such request you must state your email, full name, mailing address, and telephone number. . .

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