CERTIFICATE

EC Certificate No. 1434-MDD-322/2020

Full Quality Assurance System
Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Osatu S. Coop

Edificio Zearrekobuelta
Subida de Areito 5
Ermua 48260 SPAIN

for the design, manufacture and final inspection of
medical devices, class IIb

Electrocardiographic monitoring systems and defibrillators, with their respective accessories

The list of medical devices covered by this certificate is provided in the Annex 1

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 17.08.2020 to 23.04.2023

The date of issue of the Certificate: 17.08.2020

The date of the first issue of the Certificate: 12.04.2019

CE 1434

Issued under the Contract No. MD-266/2019
Application No: 864/2019
Certificate bears the qualified signature.
Warsaw, 17/08/2020
Module H2/3/4/5

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.08.18 16:00:52 +02'00'
Vice-President

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	Osatu S.Coop
Manufacturer address and contact details	Edificio Zearrekobuelta, Subida de Areitio, 5 48260 Ermua – Vizcaya - Spain Phone: + 34 943 170 220 info@bexencardio.com www.bexencardio.com
Single Registration Number (SRN) (if available)	ES-MF-000004710

Authorised Representative name (if applicable)	Not applicable
Authorised Representative address and contact details	Not applicable
Single Registration Number (SRN) (if available)	Not applicable

Notified body name (if applicable)	See attached schedule
Notified body number (if applicable)	See attached schedule
Directive Certificate number(s)	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.

to which this confirmation is made (if applicable)	
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)

[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

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:

- ☐ 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.

✓ Expired/expires *after* 20 March 2023:

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 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.

➢ Upclassified 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.
- ☐ 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	Osatu S.Coop
Location & Date	Ermua, December 15, 2023
Signature, Print Name, Title	Oxel Etxebarria Etxagibel Managing Director
Contact details (email)	info@bexencardio.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)
REANIBEX 100	1434-MDD-322/2020	23.04.2023	POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A. (PCBC) Number: 1434	DQS Medizinprodukte GmbH Number: 0297	31.12.2027	Not applicable
REANIBEX 300	1434-MDD-322/2020	23.04.2023	POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A. (PCBC) Number: 1434	DQS Medizinprodukte GmbH Number: 0297	31.12.2027	Not applicable
REANIBEX 500	1434-MDD-322/2020	23.04.2023	POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A. (PCBC) Number: 1434	DQS Medizinprodukte GmbH Number: 0297	31.12.2027	Not applicable

[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)

REANIBEX 700	1434-MDD-322/2020	23.04.2023	POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A. (PCBC) Number: 1434	DQS Medizinprodukte GmbH Number: 0297	31.12.2027	Not applicable
REANIBEX 800	1434-MDD-322/2020	23.04.2023	POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A. (PCBC) Number: 1434	DQS Medizinprodukte GmbH Number: 0297	31.12.2027	Not applicable
REANIBEX DataLink	1434-MDD-201/2019	23.04.2023	POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A. (PCBC) Number: 1434	DQS Medizinprodukte GmbH Number: 0297	31.12.2027	Not applicable
REANIBEX DataCloud	1434-MDD-201/2019	23.04.2023	POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A. (PCBC) Number: 1434	DQS Medizinprodukte GmbH Number: 0297	31.12.2027	Not applicable

POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

Warsaw, 06-06-2023

PCBC.BM.540.2023.MP

Osatu S. Coop

Edificio Zearrekobuelta
Subida de Areito 5
Ermua 48260 SPAIN

To Whom It May Concern,

The Notified Body - Polish Centre for Testing and Certification hereby confirms that continues to be responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices: **AED Defibrillator - REANIBEX 200, 300, 100 and ECG Monitor and Defibrillator – REANIBEX 500, 700, 800; ELIFE 700; RELIFE 700** manufactured by **Osatu S. Coop** with its registered office in Edificio Zearrekobuelta Subida de Areito 5, Ermua 48260 SPAIN, covered by the EC Certificate 1434-MDD-322/2020. Therefore, pursuant to Art. 120 par 3e of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices amended by the Regulation Regulation (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, EC certificate 1434-MDD-322/2020 remains valid.

Yours Sincerely,

Tomasz Koeber

Elektronicznie podpisany
przez Tomasz Artur Koeber
Data: 2023.06.06 18:04:54
+02'00'

Head of Medical Devices Certification Department

PCBC, NB 1434

POLISH CENTRE FOR
TESTING AND CERTIFICATION