



CERTIFICATE

EC Certificate No. 1434-MDD-201/2019
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 IIa

Electrocardiographic Monitoring Systems and Defibrillators,
with their respective accessories

List of devices covered by this certificate is given in the Annex no. 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 12.04.2019 to 23.04.2023

The date of issue of the Certificate: 12.04.2019



Application No: 674/2019

Module H

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

Michał Pachowski. Ph.D.
President



Certificate No. **1434-MDD-201/2019**
Issued under the Contract No. **MD-44/2019**
Bears the PCBC hologram
Warszawa, 12.04.2019



ANNEX NO. 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No **1434-MDD-201/2019**

The product detailed below are covered under the scope of this certificate:

Product Family	Model/Type
Transmission Data System	REANIBEX DATA LINK
	REANIBEX DATA Cloud

CE 1434

Michał Pachowski. Ph.D.
President



Annex no. 1 to certificate No. **1434-MDD-201/2019**
Issued under the Contract No. **MD-44/2019**
Bears the PCBC hologram.
Warsaw, 12.04.2019



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



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
Vice-President

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



ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-322/2020

List of medical devices covered by the certificate:

Product Family	Model/Type
AED Defibrillator	REANIBEX 200
	REANIBEX 300
	REANIBEX 100
ECG Monitor and Defibrillator	REANIBEX 500
	REANIBEX 700
	ELIFE 700
	RELIFE 700
	REANIBEX 800



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

Vice-President