

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

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



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



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Vice-President