



# 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

**Vice-President**