

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,

Head of Medical Devices Certification Department PCBC, NB 1434



