Patient Monitors – Central Monitoring Systems – Defibrillators



EC DECLARATION OF CONFORMITY

No: 05.0-EC-11.0 /en

The undersigned, Marcin Śliwa, on behalf of the company EMTEL Śliwa sp. k. Address: A. Mickiewicza 66, 41-807 Zabrze, Poland, phone +48 32 271 90 13, fax +48 32 271 57 27 herewith in his sole responsibility declares that the product

Defibrillator: DefiMax biphasic

and all its configurations

Medical Products Class IIb (Annex 9, rule 9 and 10)

- is in conformity with the Essential Requirements and provisions of the Council Directive 93/42/ EEC - Medical Devices and Medical Devices Act of 20 May 2010 and meet the requirements of the relevant harmonized standards.

Conformity assessment was conducted in cooperation with Notified Body TÜV NORD Polska sp. z o.o., ul. Mickiewicza 29, 40-085 Katowice, Polska, NB number 2274, according the procedure set out in Annex 2 of Directive 93/42/EEC (except clause 4). This declaration is valid referring to Notified Body certificate Reg. - No. TNP/MDD/0360/102/2021.

PlaceZabrze

Date......19.01.2021.....

Signature

Marcin Śliwa

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