progetti
Medical Equipment Solutions

Declaration of EC conformity

to council
Directive 93/42/EEC of 14 June 1993
and subsequent amendments concerning medical devices

MANUFACTURER :	**PROGETTI S.r.l.** Strada del Rondello, 5 10028 Trofarello (TO) - ITALY
PRODUCT:	Defibrillator
MODEL:	**Rescue LIFE**
GMDN Code:	**17882**
CLASSIFICATION:	**II b**
STANDARDs REFERENCES:	**UNI CEI EN ISO 13485:2016** **EN 60601-1:2006+A1:2013+A12:2014, EN 60601-1-2:2010, EN 60601-2-4:2011, EN 60601-2-27:2014, EN 60601-2-31:2008+A1:2011, EN 62353:2014, EN 62366-1:2015, EN 60601-1-6:2010, EN 62304:2006, EN ISO 14971:2012, EN ISO 15223-1:2012, MEDDEV 2.7/1 Rev.4, MEDDEV 2.12-1 Rev.8, MEDDEV 2.12/2 Rev.2**
SERIAL NUMBER**:**	*

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL **DIRECTIVE 93/42/EEC** OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES, ACCORDING TO ESSENTIAL REQUIREMENTS AND SUBSEQUENT AMENDMENTS.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
ALSO, THE **DEFIBRILLATOR** IS MANUFACTURED BASED ON: **DIRECTIVE 2011/65/EEC** AND ITS SUBSEQUENT AMENDMENTS (***ROHS***). THE PRODUCT CONCERNED HAS BEEN MANUFACTURED UNDER A QUALITY MANAGEMENT SYSTEM ACCORDING TO **ANNEX II OF DIRECTIVE 93/42/EEC.**

NOTIFIED BODY:	MIT International Testing S.r.l. Via Moscova, 11 20017 Rho - MI, ITALY
EC MARK:	CE 0068 Digitally signed by Grosu Marina Date: 2020.03.02 11:54:41 EET Reason: MoldSign Signature Location: Moldova
EC CERTIFICATE N°:	**0068/QCO – DM/025-2015**
EXPIRE DATE:	**2021, May 06th**
FIRST ISSUE:	2015, May 06th
PLACE, DATE :	TROFARELLO (TO) – **2019, 09th January**
SIGNATURE:	Dr. CESARE MANGONE MANAGEMENT REPRESENTAIVE

*IF YOU WANT RECEIVE DEDICATED DECLARATION OF CONFORMITY FOR YOUR DEVICE SERIAL NUMBER AND/OR UPDATED ONE, PLEASE CONTACT PROGETTI S.R.L. OFFICE TO THE EMAIL info@progettimedical.com