EU Declaration of conformity

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

PRODUCT:	**Infusion Pump**
MODEL:	**PG-807i**
GMDN:	13215
CLASS:	IIb
MANUFACTURER:	PROGETTI s.r.l. Strada del Rondello, 5 10028 Trofarello (TO) ITALY
STANDARD REFERENCES:	**EN 1041:2008+A1:2013, EN ISO 13485:2016, EN ISO 14971:2012 EN ISO 15223-1:2016, EN 60601-1:2006+A1:2013+A12:2014, EN 60601-1-2:2015, EN 60601-1-4:1996+A1:1999, BS EN 60601-1-6:2010+A1:2015 EN 60601-1-8:2007+A1:2013, EN 60601-2-24:2015, EN 62366:2008, EN 62133:2013, EN 62304:2006+AC:2008, Directive 2006/42/EC**
SERIAL NUMBER:	*

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE PROVISIONS OF THE FOLLOWING EC COUNCIL DIRECTIVES AND STANDARDS. THE PRODUCT CONCERNED HAS BEEN MANUFACTURED UNDER A QUALITY MANAGEMENT SYSTEM ACCORDING TO **ANNEX II OF DIRECTIVE 93/42/EEC**. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER AND THE NOTIFY BODY.
THE **INFUSION PUMPS** ARE MANUFACTURED BASED ON LEAD – FREE COMPONENTS, ACCORDING TO ROHS, DIRECTIVE 2011/65/CEE AND ESSENTIAL REQUIREMENTS AND SUBSEQUENT AMENDMENTS.

NOTIFIED BODY:	MTIC INTERCERT® N°0068 - *MTIC InterCert S.r.l.* Via Moscova,11 20017 Rho (MI) - ITALY
IDENTIFICATION NUMBER:	CE 0068
CERTIFICATE No.:	**0068/QCO-DM/017-2018**
FIRST ISSUE:	2018, 2nd March
EXPIRY DATE:	**2021, 2nd March**
PLACE, DATE OF ISSUE:	TROFARELLO (TO) - 2019, 14th October
SIGNATURE:	Dr. CESARE MANGONE President & CEO

*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