





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

PRODUCT:	Syringe Pump
MODEL:	PG-907s
GMDN:	13217
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 **SYRINGE PUMPS** ARE MANUFACTURED BASED ON LEAD – FREE COMPONENTS, ACCORDING TO ROHS, DIRECTIVE 2011/65/CEE AND ESSENTIAL REQUIREMENTS AND SUBSEQUENT AMENDMENTS.

NOTIFIED BODY:		N°0068 - MTIC InterCert S.r.l. Via Moscova,11 20017 Rho (MI) - ITALY
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IDENTIFICATION NUMBER:	 0068
CERTIFICATE No.:	0068/QCO-DM/017-2018
FIRST ISSUE:	2018, 2 nd March
EXPIRY DATE:	2021, 2nd March
PLACE, DATE OF ISSUE:	TROFARELLO (TO) - 2019, 14 th 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

