EC-Declaration of Conformity

Manufacturer:

Name	:	METKO Medikal ve Tıbbi Cihazlar Dış Ticaret Ltd. Şti.
Address	:	İvedik O. S. B. Ağaç İşleri Sanayi Sitesi 1354 Cad. 1358 Sok. No:9 06378 Yenimahalle - Ankara \ Turkey
Tel	:	+ 90 312 387 12 46 (pbx)
Fax	:	+ 90 312 387 12 51
E-mail	:	metko@metkoltd.com
Web	:	www.metkoltd.com

Authorized European Representative:

Name	:	Medset Medizintechnik GmbH
Address	:	Curslacker Neuer Deich 66 D-21029 Hamburg \ Germany
Tel	:	0049 40 725 822- 0
Fax	:	0049 40 725 822-11
E-mail	:	info@medset.com
Web	:	www.medset.com

Product: Sterile Disposable Pressure Transducer

Reference Numbers:
TKBT-103, TKBT-203

Classification: Class II b Medical Device, Annex IX Rule 10
Conformity Assessment Procedure: Annex II.3 (excluding section 4)
GMDN Code: 45275

We herewith declare that the above mentioned products meet the Essential requirements and conform to the Medical Device Directive 93/42/EEC with 2007/47/EC amendment.

Applied Standards:
EN ISO 9001:2015, EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008+A1:2013, EN ISO 11737-1:2018, EN ISO 11737-2:2009, IEC 60601-2-34:2011, ANSI/AAMI BP22-1994, EN ISO 11607-1:2017, EN ISO 11607-2:2017, EN ISO 14155:2011, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-7:2008/AC:2009, ISO 10993-5:2009, EN ISO 10993-10:2013, ISO 10993-11:2017, AAMI/ISO 11135:2014, EN ISO 14698-1:2003, EN 14698-2:2003 AC:2006, EN ISO 14644-3:2005, EN ISO 14644-4:2001, ISO 14644-5:2004, EN ISO 14644-1:2015, EN 62366-1:2015

Notified Body:

Name:	KIWA Belgelendirme Hizmetleri A.Ş.
Address:	ITOSB 9. Cadde No:15 Tepeören-Tuzla İstanbul / Turkey
Identification Number:	1984

Number of Certificate:	1984-MDD-10-075
Start of CE Mark:	08.01.2013
Duration of Validity:	29.05.2020 – 27.05.2024
Revision Date:	29.05.2020

Signature:

Digitally signed by Prodan Sveatoslav
Date: 2021.03.22 17:30:10 EET
Reason: MoldSign Signature
Location: Moldova

Name: Filiz ERSOY
Position: Company Manager

Expiry date of declaration is expiry date of CE certificate.