

EC-Declaration of Conformity

Manufacturer:

Name : METKO Medikal ve Tıbbi Cihazlar Dış Ticaret Ltd. Şti.
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Authorized European Representative:

Name : Medset Medizintechnik GmbH
Address : Curslackner Neuer Deich 66 D-21029 Hamburg \ Germany
Tel : 0049 40 725 822- 0
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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 conforms to the Medical Device Directive 93/42/EEC with Medical Device Directive 2007/47/EC.

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, 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, EN ISO 10993-10:2013, EN ISO 10993-11:2017, AAMI/ISO 11135-1:2014, 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, RoHS 2011/65/EU

Notified Body:

KIWA Certification Services Inc.
ITOSB 9. Cadde No:15 Tepeören-Tuzla İstanbul / Turkey

EC-Mark:

Number of Certificate: 1984-MDD-10-075

Start of CE Mark: 08.01.2013

Duration of Validity: 16.04.2019 – 20.11.2020

Date of Issue: 16.04.2019

Signature:**Name:**

Filiz ERSOY

Position:

Company Manager