

EC Declaration of Conformity

Declaration No.: 01-2012

Manufacturer: MESI, development of medical devices, Ltd.
Letališka cesta 3C
SI-1000 Ljubljana, SLOVENIA

Product category: Noninvasive Ankle-Brachial Pressure Index Measurement unit
GMDN code: 58928
Product Name: Automated Ankle-Brachial Pressure Index Measuring Device, ABPI MD
Model/Type: ABPIMDD/MA0001
Classification: IIa (Anex II, Rule 10)

We declare under our sole responsibility that the above mentioned product is fully complying with the essential requirements of Directive 93/42/EEC of medical devices.

The product was a subject of conformity assessment procedure described in Annex II (Full quality assurance system) excluding the point 4 of Annex II.

STANDARDS APPLIED

EN 60601-1:2006	EN 1060-3:1997+A2:2009
EN 60601-1-2:2007	EN 1060-4:2004
EN 60601-1-6:2010	EN 980:2008
EN 60601-2-30:2000	EN ISO 14971:2009
EN 80601-2-30:2010	EN ISO 13485:2003/AC:2009
EN 1060-1:1995+A2:2009	EN ISO 10993-1:2009

EN ISO 14971:2012

EN ISO 13485:2012
EN ISO 10993-1:2009
1000 Ljubljana, Slovenia
Notified Body No. 1304

EC CERTIFICATE

No: MDD-037
Certification date: 2015-06-08
Issue: 5/2015-06-08
Valid until: 2018-05-31

Ljubljana, 10.6.2015




Jakob Šušterič, CEO