

# EC Declaration of Conformity

Declaration No.: 05-2018

**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 (Annex IX, 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+A1:2013	EN ISO 13485:2016
EN 60601-1-2:2007	EN ISO 15223-1:2016
EN 80601-2-30:2010+A1:2015	EN ISO 10993-1:2009
EN 60601-2-30:2000	EN ISO 81060-2:2012
EN 1060-3:1997+A2:2009	EN 60601-1-6:2010
EN 1060-4:2004	EN 62304:2006+A1:2015
EN ISO 14971:2012	

## NOTIFIED BODY

SIQ, Slovenian Institute of Quality and Metrology  
Tržaška cesta 2  
1000 Ljubljana, Slovenia  
Notified Body No. 1304

## EC CERTIFICATE

No: MDD-037  
Certification date: 2012-05-09  
Issue: 7/2018-05-31  
Valid until: 2021-05-31

Ljubljana, 31.5.2018

Jakob Šušterič, CEO