

EC Declaration of Conformity

Declaration No.: 05-2021

Manufacturer: MESI, Ltd.
Leskoškova cesta 11a
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 Concerning medical devices and Directive (EU) 2015/863.

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 15223-1:2016 |
| EN 60601-1-2:2015 | EN ISO 10993-1:2009/AC:2010 |
| EN 80601-2-30:2010+A1:2015 | EN 80601-2-30:2010/A1:2015 |
| EN 1060-3:1997+A2:2009 | EN 60601-1-6:2010+A1:2015 |
| EN 1060-4:2004 | EN 62304:2006+A1:2015 |
| EN ISO 14971:2012 | |
| EN ISO 13485:2016 | |

NOTIFIED BODY

SIQ, Slovenian Institute of Quality and Metrology
Mašera-Spasičeva ulica 10
1000 Ljubljana, Slovenia
Notified Body No. 1304

EC CERTIFICATE

No: MDD-037
Certification date: 2012-05-09
Issue: 9/2021-05-12
Valid until: 2024-05-26

Ljubljana, 25.05.2021


Jakob Šušterič, CEO