

# EC Declaration of Conformity

Declaration No.: 10-2017

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

**Product category:** Wireless multichannel electrocardiograph  
**GMDN code:** 16231  
**Product Name:** MESI mTABLET ECG diagnostic system  
**Model/Type:** MTABSYSECG  
**Classification:** IIa (Annex II, Rule 10)

We declare under our sole responsibility that the above mentioned product is fully complying with the essential requirements of Directive 92/42/EEC Concerning medical devices, RoHS Directive 2002/95/EC and Radio Equipment Directive (RED) 2014/53/EU.

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 1064:2005/A1:2007
EN 60601-1-6:2010/A1:2015	EN 303 446-1:2017
EN 60601-2-25:2015	EN ISO 14971:2012
EN 62304:2006/A1:2015	EN ISO 10993-1:2009/AC:2010
EN 62366:2008	EN ISO 13485:2012/AC:2012
EN 60601-1-2:2015	EN 980:2008

## NOTIFIED BODY

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

## EC CERTIFICATE

No: MDD-081  
Certification date: 2017-10-02  
Issue: 01/2017-10-02  
Valid until: 2020-10-02

Ljubljana, 09.10.2017

  
Jakob Šušterič, CEO