MESI
Simplifying Diagnostics

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