DECLARATION OF CONFORMITY
(Directive 2014/53/EU)

Manufacturer
A. Menarini Diagnostics S.r.l.
Via Sette Santi 3
50131 Firenze, Italy

Product Category according to Directive 98/79/EC for in vitro diagnostic medical devices
Blood glucose measuring meter for self-testing

Description	**Product Name**
Blood Glucose Meter	GlucoMen® areo 2K, GlucoMen® areo, GLUCOFIX® TECH 2K, GLUCOFIX® TECH, (any serial number)

We hereby declare under our sole responsibility that the products are in conformity with Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) relating to the making available on the market of radio equipment.

Conformity assessment route: Annex II applied (Directive 2014/53/EU)

GlucoMen areo 2K

Essential Requirements Radio Equipment Directive 2014/53/EU	**Standards**
Safety & Health (Article 3.1a)	IEC 62368-1:2014; EN 62368-1:2014+A11:2017; EN 62479:2010
EMC (Article 3.1b)	EN 301 489-1 V2.1.1; EN 301 489-3 V2.1.1; EN 60601-1-2:2007+AC:2010 EN 61326-1:2013; EN 61326-2-6:2013
Radio Spectrum Efficiency (Article 3.2)	EN 300 330 V2.1.1
Frequency Band(s): 13.56MHz	
Maximum power: 0.67 nW	

GlucoMen areo

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Radio Spectrum Efficiency (Article 3.2)	EN 300 330 V2.1.1
Frequency Band(s): 13.56MHz	
Maximum power: 0.0077 mW	

GLUCOFIX® TECH 2K

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Radio Spectrum Efficiency (Article 3.2)	EN 300 330 V2.1.1
Frequency Band(s): 13.56MHz	
Maximum power: 0.67 nW	

GLUCOFIX® TECH

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Radio Spectrum Efficiency (Article 3.2)	EN 300 330 V2.1.1
Frequency Band(s): 13.56MHz	
Maximum power: 0.0042 mW	

Signature: _____ Date: 2017-11-10

Dr. Marco Di Carlo
Proxy and Legal Representative

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