

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

Blood Glucose Meter

Product Name

GlucoMen[®] areo GK, GlucoMen[®] areo 2K, GlucoMen[®] areo, GLUCOFIX[®] TECH GK, 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

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 301 489-17 V3.1.1; EN 60601-1-2:2007+AC:2010
BS EN IEC 61326-1:2021; BS EN IEC 61326-2-6:2021

Radio Spectrum Efficiency
(Article 3.2)

EN 300 328 V2.1.1

Frequency Band(s): 13.56MHz

Maximum power: 0.0077 mW

GLUCOFIX[®] TECH

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;
BS EN IEC 61326-1:2021; BS EN IEC 61326-2-6:2021

Radio Spectrum Efficiency
(Article 3.2)

EN 300 330 V2.1.1

Frequency Band(s): 13.56MHz

Maximum power: 0.0042 mW

Glucomen areo 2K & GLUCOFIX TECH 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; BS EN IEC 61326-1:2021; BS EN IEC 61326-2-6:2021
Radio Spectrum Efficiency (Article 3.2)	EN 300 330 V2.1.1
Frequency Band(s): 13.56MHz	
Maximum power: 0.0000067 mW	

GLUCOFIX® TECH GK & Glucomen areo GK

Essential Requirements Radio Equipment Directive 2014/53/EU	Standards
Safety & Health (Article 3.1a)	EN 61010-2-101:2017 with EN 61010-1:2010 + A1:2019 EN 62479:2010
EMC (Article 3.1b)	EN 301 489-1 V2.2.3; EN 301 489-3 V2.1.1; EN 61326-1:2013; EN 61326-2-6:2013 IEC 61326-1:2020 IEC 61326-2-6:2020
Radio Spectrum Efficiency (Article 3.2)	EN 300 330 V2.1.1
Frequency Band(s): 13.56MHz	
Maximum power: -25 DbμA/m	

Signature: _____



Dr. Fabio Piazzalunga
General Manager and Legal Representative

Date: 2022-12-12