



DECLARATION OF CONFORMITY

2.0, CURRENT

Approved

18-Dec-2020

Manufacturer

A. MENARINI DIAGNOSTICS S.R.L.
Via Sette Santi 3
50131 Firenze, Italy

Product Category

Blood glucose measuring systems for self testing and other systems for self testing

Model

GlucoMen® areo blood glucose measuring system

Comprising:

GIVD Code	Description
21.07.10.01	GlucoMen® areo
11.70.01.01	GlucoMen® areo Sensor
11.70.01.50	GlucoMen® areo Control N
11.70.01.50	GlucoMen® areo Control H

Classification

Device in Annex II list B
(Directive 98/79/EC for in vitro diagnostic medical devices)

Conformity assessment route

Annex IV applied
(Directive 98/79/EC for in vitro diagnostic medical devices)

We hereby declare that the above mentioned products meet the provisions of the Directive 98/79/EC (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) concerning in vitro diagnostic medical devices.

The Quality system established and maintained by the manufacturer, along with the relevant technical documentation, is submitted to periodical surveillance by the

Notified Body

TÜV SÜD Product Service GmbH
Ridlerstrasse 65, München, Germany, D-80339
Id-No. 0123

EC certificate: V1 030532 0020 Rev. 01

Valid until: 2024-05-26

The present declaration is valid until 2024-05-26.

Signature: _____

Dr. Fabio Piazzalunga
General Manager and Legal Representative

Date: 2020-12-14