



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07



Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In-Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 5)
(List A and B and devices for self-testing)

No. V1 030532 0020 Rev. 01

Manufacturer:

A. Menarini Diagnostics S.r.l.

Via Sette Santi, 3
50131 FIRENZE
ITALY

Product Category(ies): Blood glucose measuring systems for self testing and other systems for self testing

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V1_030532_0020_Rev.01

Report no.: ITA1628227

Valid from: 2020-12-14

Valid until: 2024-05-26

Date, 2020-12-14

Christoph Dicks
Head of Certification/Notified Body

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Model(s):

Systems for Blood Glucose self-testing composed by Meter, Test Strips and Control Solutions:

GlucoMen® areo
GLUCOFIX® TECH
GlucoMen® READY

Systems for Blood Glucose/Ketone self-testing composed by Meter, Glucose Test Strips, Ketone Test Strips, and Glucose/Ketone Control Solutions

GLUCOFIX® miò plus
GLUCOFIX® Premium
GlucoMen® LX PLUS
GlucoMen® LX2

System for Blood Glucose/Ketone and Cholesterol self-testing composed by Meter, Glucose Test Strips, Ketone Test Strips, Cholesterol Test Strips, Glucose/Ketone Control Solutions and Cholesterol Control Solutions

GlucoMen® LX3

Systems for Blood Glucose/Ketone self-testing composed by Meter, Glucose Test Strips, Ketone Test Strips, Glucose Control Solutions and Ketone Control Solutions

GlucoMen® areo 2K
GLUCOFIX® TECH 2K

Facility(ies):

A. Menarini Diagnostics S.r.l.
Via Lungo l'Enza 7, 50012 Bagno a Ripoli (FI), ITALY

A. Menarini Diagnostics S.r.l.
Via Sette Santi, 3, 50131 FIRENZE, ITALY