



Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV
excluding (4, 6)

(List A and B and devices for self-testing)

No. V1 17 05 30532 019

Manufacturer: **A. Menarini Diagnostics S.r.l.**

Via Sette Santi, 3
50131 FIRENZE
ITALY



Facility(ies):

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

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

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

Model(s): **see Attachment**

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. See also notes overleaf.

Report no.: ITA894831

Valid from: 2017-09-12

Valid until: 2022-09-11



Date, 2017-07-27

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Attachment for Certificate no V1 17 05 30532 019
dated 2017-07-27

Model Name:

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

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

Munich, CRT2, 2017-07-27

Stefan Preiß