EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60146513 0001

Report No.: 21246563 019

Manufacturer:
MED TRUST Handelsges.m.b.H.
Gewerbepark 10
7221 Marz
Österreich

Products:
In-vitro-Diagnostic Monitoring Systems for Self-Testing

(see attachment for products included)
Replaces Certificate, Registration No.: HL 60110343 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Effective Date: 2020-08-21

Date: 2020-08-21

Notified Body

Katja Mierisch

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HL 60146513 0001
Report No.: 21246563 019

Manufacturer: MED TRUST Handelsges.m.b.H.
Gewerbepark 10
7221 Marz
Österreich

Products included:

- Blood Glucose Meters
- Blood Glucose and Cholesterol Meters
- Blood Glucose and Ketone Meters
- Blood Glucose, Cholesterol and Uric Acid Meters
- Glucose Control Solutions
- Cholesterol Control Solutions
- Ketone Control Solutions
- Uric Acid Control Solutions
- Glucose Test Strips
- Cholesterol Test Strips
- Ketone Test Strips
- Uric Acid Test Strips

Date: 2020-08-21

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Katja Mierisch