

EC Certificate



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

Registration No.: HL 1178843-1

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

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

Products included:

- Blood Glucose Meters
- Blood Glucose and Cholesterol Meters
- Blood Glucose and Ketone Meters
- Blood Glucose, Cholesterol and Uric Acid Meters
- HbA1c Meters
- Glucose Control Solutions
- Cholesterol Control Solutions
- Ketone Control Solutions
- Uric Acid Control Solutions
- HbA1c Control Solutions
- Glucose Test Strips
- Cholesterol Test Strips
- Ketone Test Strips
- Uric Acid Test Strips
- HbA1c Test Strips

Replaces Certificate, Registration No.: HL 60146513 0001

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.

Report No.: 1104380-20

Effective date: 11.03.2022

Expiry date: 26.05.2025

Issue date: 11.03.2022



Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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.