EU Certificate

for the assessment of the quality management system

according to Regulation on In-vitro Diagnostic Medical Devices (EU) 2017/746 Annex IX Chapter I+III

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the manufacturer

Analyticon Biotechnologies GmbH

Single Registration Number (SRN): DE-MF-000016251
Am Mühlenberg 10, 35104 Lichtenfels, Germany

applies a quality management system according to Annex IX Chapter I+III of the regulation on in-vitro diagnostic medical devices (EU) 2017/746 for the devices listed in the annex. This certificate is based on the assessments listed in CNo51519-00 and is only valid in conjunction with the successful completion of the annual surveillance audits.

EU Certificate no.: 51519-70-00-00

Certificate valid from: 2024-12-02
Certificate valid to: 2027-01-10

Digital unterschrieben von CORD JOHANNES WIORA
Datum: 2024-12-02 17:36:36+01:00

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-100

DEKRA Certification GmbH, Stuttgart 2024-12-02
Notified Body ID: 0124

Annex to the EU Certificate no. 51519-70-00-00

Following devices/device categories are included in this certificate:

Class B near-patient test devices

Name of the device/ device category:

Urine Test Strips for visual and semiautomated evaluation

Basis-UDI-DI: 426003371CSLY

Intended use:

level 1: Class B for near-patient testing

- level 2: IVR0608 Devices intended to be used for screening, determination or monitoring of physiological markers
    - level 3: W0101060204: urine multi-constituent test strips (manual)
        - level 4: 426003371CSLY
            - level 5: Urine Test Strips for visual and semiautomated evaluation