



EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX, Chapter II

No. V76 077568 0009 Rev. 00

Manufacturer: **Analyticon Biotechnologies GmbH**
Am Mühlberg 10
35104 Lichtenfels
GERMANY

SRN Manufacturer - DE-MF-000016251

The technical documentation has been evaluated in accordance with Regulation (EU) 2017/746,
Annex IX Chapter II with a positive result.

Details on devices covered by the technical documentation are described on the following page(s).
The report referenced below summarises the results of the assessment and includes reference to
relevant CS, harmonised standards and test reports.

If class B or C self-/near-patient testing are covered by this certificate, the assessment was conducted
according to section 4 and 5.1. An EU Quality Management System Certificate in accordance with
Annex IX Chapter I is required before placing them on the market.

If class C companion diagnostics devices are covered by this certificate, the assessment was
conducted according to section 4 and 5.2. An EU Quality Management System Certificate in
accordance with Annex IX Chapter I is required before placing them on the market.

If class D devices are covered by this certificate, verification of batches of manufactured devices
according to Annex IX Sections 4.12 and 4.13 is applicable. An EU Quality Management System
Certificate in accordance with Annex IX Chapter I is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV
SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V76 077568 0009 Rev. 00

Report No.: 713375337_V76
Valid from: 2025-12-01
Valid until: 2029-12-01

Marta Carnielli
Head of Certification IVD

Issue date: 2025-11-27



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| | |
|--------------------------|--|
| Classification: | Class B near-patient testing |
| Basic UDI-DI: | 426003371CSLY |
| Intended Purpose: | <p>Urine test strip as an in vitro diagnostic medical device for use as a preliminary screening test for diabetes, liver diseases, haemolytic diseases, urogenital and kidney disorders and metabolic abnormalities by the rapid semi-quantitative determination of various combinations of the parameters ascorbic acid, bilirubin, blood, creatinine, glucose, ketones, leucocytes, microalbumin, nitrite, pH-value, protein, specific gravity and urobilinogen in human urine.</p> <p>The product is designed for professional use and may be used in a near-patient environment.</p> <p>All urine test strips are used for visual analysis. The system urine test strips may also be used on semi-automatic urine analyzers.</p> |
| Device Group: | IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers |
| Device(s): | see separate table Page 3 and 4 |

| Model | Ref. No. |
|---------------------------|----------|
| CombiScreen® Glu Plus | 94501 |
| CombiScreen® Nitrit Plus | 94506 |
| CombiScreen® 3 Plus | 94508 |
| CombiScreen® 3 Plus | 94108 |
| CombiScreen® 5+N Plus | 94535 |
| CombiScreen® 5+N Plus | 94135 |
| CombiScreen® 5+Leuko Plus | 94517 |
| CombiScreen® 5+Leuko Plus | 94117 |
| CombiScreen® 9 Plus | 94115 |
| CombiScreen® 9+Leuko Plus | 94250 |
| CombiScreen® 9+Leuko Plus | 94200 |
| CombiScreen® 10 SL Plus | 94120 |
| CombiScreen® 5SYS Plus | 94109 |
| CombiScreen® 7SYS Plus | 94110 |
| CombiScreen® 7SYS Plus | 94110A |
| CombiScreen® 11 SYS Plus | 94100 |
| CombiScreen® 11 SYS Plus | 94150 |
| CombiScreen® mALB/CREA | 94025 |
| CombiScreen® 12SYS Plus | 94400 |
| CombiScreen® 12SYS Plus | 94450 |



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| | |
|------------------------|---------|
| UDStrip-12 | 967 200 |
| UDStrip-12 | 967 201 |
| CombiScreen® GP | 93104 |
| CombiScreen® 3 | 93108A |
| CombiScreen® GAK | 93107 |
| CombiScreen® GAK | 93107A |
| CombiScreen® GPK | 93105 |
| CombiScreen® 10SL | 93120 |
| CombiScreen® 10SL | 93120A |
| CombiScreen® 10SL | 93120B |
| CombiScreen® 10SL | 92120 |
| CombiScreen® 10 SL ECO | 91120 |
| CombiScreen® 10 SL ECO | 91120A |
| CombiScreen® 11SYS | 93100 |
| CombiScreen® 11SYS | 93150 |
| meditrol® 3 PROTECT | 103 |

| | |
|-------------------------------|--------------|
| meditrol® 6 PROTECT | 106 |
| meditrol® 10+Leuko PROTECT | 121 |
| Ratiomed® EASYscreen 5+N | 200235 |
| Ratiomed® EASYscreen 10SL | 200220 |
| RAPID-SCAN 6-SN + | 01-04-11 |
| RAPID-SCAN 8SL + | 01-04-21 |
| RAPID-SCAN 7SYS + | 01-04-41 |
| RAPID-SCAN 11SYS + | 01-04-31 |
| Megutest 7 + Vitamin C Filter | 2012 |
| PM-U10-Test | UT10100 |
| Uri-Screen 10 | 20110 |
| Uri-Screen 11 | 20111 |
| WiduMed Urinteststreifen 10 | wi-urs10-100 |
| WiduMed Urinteststreifen 5 | wi-urs5-100 |
| URINE SCREEN 10 | 24073 |
| URINE SCREEN 11 | 24074 |



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zflg.de
 BS-IVDR-099



Product Service

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The validity of this certificate -none-
 depends on conditions and/or
 is limited to the following:

Revision History:

| Rev. | Dated | Report | Description |
|------|------------|---------------|------------------|
| 00 | 2025-12-01 | 713375337_V76 | Initial issuance |