# Konformitätserklärung – Urin Diagnostik /
# Declaration of Conformity – Urine Diagnostics


## Analyticon Biotechnologies GmbH

**Am Mühlenberg 10,**
**35104 Lichtenfels, Germany**


Wir erklären in alleiniger Verantwortung, dass die Medizinprodukte für die In-vitro-Diagnostik
*We declare under our sole responsibility that the in vitro diagnostic medical devices*

Bezeichnung und Artikelnummer: siehe Anhang
*Description and article number: see annex*

mit folgender Klassifizierung nach der Richtlinie über In-Vitro-Diagnostika 98/79/EG
*classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC*

( ) Produkt der Liste A, Anhang II / Device of List A, Annex II
( ) Produkt der Liste B, Anhang II / Device of List B, Annex II
( ) Produkt zur Eigenanwendung, das nicht in Anhang II genannt ist /
*Device for self-testing not listed in Annex II*
(X) Sonstiges Produkt / *Other device*

allen Anforderungen der Richtlinie über In-vitro-Diagnostika 98/79/EG entspricht, die anwendbar sind.
*meet all the provisions of the directive on in vitro diagnostic medical devices 98/79/EC which apply to it.*

| | |
|---|---|
| Konformitätsbewertungsverfahren<br>*Conformity assessment procedure* | IVD 98/79/EG, Artikel 9 (1) und Anhang III /<br>*IVD 98/79/EC Article 9 (1) and Annex III* |
| EDMA-Code und Registrierungsnummer<br>*EDMS-Code and Registration-No.* | siehe Anhang<br>*see annex* |
| Konformitätsbewertungsstelle<br>*Notified Body (if consulted)* | nicht erforderlich, die Bewertung wurde in Eigenverantwortung des Herstellers durchgeführt<br>*not applicable, evaluation was carried out under the manufacturer's own responsibility* |

Ort, Datum / *Place, date*

Lichtenfels, 27.04.2022

Name und Funktion / *Name and function*

Dr. Jürgen Schmich
(Sicherheitsbeauftragter gem. §30(2) MPG)
*(safety officer for med. devices acc. §30(2) MDD)*

**Analyticon Biotechnologies GmbH**
**Am Mühlenberg 10,**
**35104 Lichtenfels, Germany**

**Anhang zur Konformitätserklärung – Urin Diagnostik /**
**Declaration of Conformity, Annex – Urine Diagnostics**

## CombiScreen Urine Controls

| Name | REF | EDMS-Code | Reg.-Nr. |
|---|---|---|---|
| CombiScreen® Dip Check | 93010 | 11.50.90.02.00 | DE/CA30/56863/D/019/Ä |
| CombiScreen® Drop Check | 93015 | 11.50.90.02.00 | DE/CA30/56863/D/019/Ä |

Analyticon Biotechnologies GmbH, Am Mühlenberg 10, 35104 Lichtenfels

**TO WHOM IT MAY CONCERN**

17th June, 2025

## Manufacturer's Declaration

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain in vitro diagnostic medical devices, in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body and/or
- the compliance of the devices and us, as their manufacturer, with the conditions for the continued placing on the market and putting into service

We, **Analyticon Biotechnologies GmbH**, based at Am Muehlenberg 10, 35104 Lichtenfels, Germany, hereby declare under our sole responsibility,

- for the device(s) listed in the attached table the conditions for the legal extension of transitional periods as required in Article 110.3b of the IVDR are met *and*
- the device(s) listed in the attached table and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

1. **Devices which were self-declared under the IVDD and require notified body involvement under the IVDR**

In case of devices for which the conformity assessment procedure pursuant to IVDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to IVDR requires the involvement of a notified body:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body for the device(s) listed in the attached table or its/their substitutes no later than:

☐ 26 May 2025 for class D devices

☐ 26 May 2026 for class C devices

☒ 27 May 2027 for class B and class A (sterile) devices

☒ Signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR for the device(s) listed in the attached table or its/their substitutes no later than:

☐ 26 September 2025 for class D devices

☐ 26 September 2026 for class C devices

☒ 27 September 2027 for class B and class A (sterile) devices

☐ We do not intend to lodge an application for conformity for the device as indicated on the attached table

☒ Device listed in the attached table

- continue to comply with the IVDD.
- were not subject to significant changes in the design and intended purpose
- do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

**2. Quality Management System (QMS)**

☒ QMS in accordance with Article 10(8) IVDR is in place.

☒ Notified body has issued the attached certificate for the IVDR-compliant QMS.

For and on behalf of Analyticon Biotechnologies GmbH

Analyticon Biotechnologies GmbH · Germany · Am Muehlenberg 10 · 35104 Lichtenfels

Dr. Britta Meißner
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Annex 1: Product list

| Product | Article No. | Classification under Regulation 2017/746 | Application planned (y/n) |
|---|---|---|---|
| CombiScreen® 9+Leuko Plus | 94200 | B | y |
| CombiScreen® 10 SL Plus | 94120 | B | y |
| CombiScreen® 5SYS Plus | 94109 | B | y |
| CombiScreen® 7SYS Plus | 94110 | B | y |
| CombiScreen® 11SYS Plus | 94100 | B | y |
| CombiScreen® 11SYS Plus | 94150 | B | y |
| CombiScreen® mALB/CREA | 94025 | B | y |
| CombiScreen® 10SL | 93120A | B | y |
| CombiScreen® 11SYS | 93150 | B | y |
| URINE SCREEN 10 | 24073 | B | y |
| URINE SCREEN 11 | 24074 | B | y |
| CombiScreen® Dip Check | 93010 | B | y |

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