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

Ort, Datum / *Place, date*	Name und Funktion / *Name and function*
Lichtenfels, 18.01.2023	Dr. Jürgen Schmich (Direktor Qualitätssicherung / Director Quality Assurance)

Analyticon Biotechnologies GmbH
Am Mühlenberg 10,
35104 Lichtenfels, Germany

Test strips visual and semi-automated systems

Name	REF	EDMS-Code	Reg.-Nr.
CombiScreen® 11SYS	93100	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 11SYS	93150	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 10SL	93120	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 10SL	93120A	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 10SL	93120B	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 3	93108A	11.70.02.02.00	DE/CA30/00017200
CombiScreen® GAK	93107	11.70.02.02.00	DE/CA30/00017200
CombiScreen® GAK	93107A	11.70.02.02.00	DE/CA30/00017200
CombiScreen® GP	93104	11.70.02.02.00	DE/CA30/00017200
CombiScreen® GPK	93105	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 11SYS PLUS	94100	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 11SYS PLUS	94150	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 11SYS PLUS	94150BC	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 10SL PLUS	94120	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 9 PLUS	94115	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 9+Leuko PLUS	94250	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 9+Leuko PLUS	94200	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 7SYS PLUS	94110	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 7SYS PLUS	94110A	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5SYS PLUS	94109	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5+Leuko PLUS	94517	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5+Leuko PLUS	94117	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5+N PLUS	94535	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5+N PLUS	94135	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 3 PLUS	94508	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 3 PLUS	94108	11.70.02.02.00	DE/CA30/00017200
CombiScreen® Glu PLUS	94501	11.70.02.02.00	DE/CA30/00017200
CombiScreen® Nitrit PLUS	94506	11.70.02.02.00	DE/CA30/00017200
CombiScreen® mALB / CREA	94025	11.70.02.02.00	DE/CA30/00017200

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
Senior Manager Regulatory Affairs & Quality Assurance
b.meissner@analyticon-diagnostics.com

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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