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TÜV SÜD Product Service GmbH · Ridlerstr. 65 · 80339 Munich · Germany

HANGZHOU BIOTEST BIOTECH CO., LTD.
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Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
077434	713266154 713331341	--- medical_devices@tuvsud.com	---	2025-09-03	1 of 27

**TÜV SÜD Product Service GmbH
Confirmation Letter
CLI 077434 0024 Rev. 01**

Reference: 713266154 | 713331341 | SH24708A01 | SH24708A02 | SH24708A03 | SH24708A04 | SH24708A05 | SH24708A06 | SH24708A07 | SH24708A08 | SH24708A12 | SH24708A13 | SH25708A01 | SH25708A02 | SH25070821_CLI | SH2470800_CLI_transfer

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2024/1860 amending Regulations (EU) 2017/746 (in the following referenced as IVDR) as regards the transitional provisions for certain in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under IVDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of IVDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of IVDR with the above stated manufacturer with the following Single Registration Number (SRN)

Single Registration Number: CN-MF-000008191

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an IVDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

Registered Office: Munich
Trade Register Munich HRB 85742
UniCredit Bank GmbH · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
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Board of Management:
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Ridlerstr. 65
80339 Munich
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- Table 2 identifies the devices for which an IVDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive or these devices did not require a Notified Body certificate under Directives.

If devices covered by certificates issued under Directive 98/79/EC (IVDD) that expired after 26. May 2022 and before 09. July 2024, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under IVDR by the date of IVDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 54(1) of IVDR or Article 92(1) of the IVDR respectively.

The transition timelines in accordance Article 110 (3) of IVDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 110 (3c) of IVDR, are shown below:

- 31. December 2027, for devices certified under IVDD
- 31. December 2027, for class D devices;
- 31. December 2028, for class C devices;
- 31. December 2029, for class B devices and for class A devices placed on the market in sterile condition

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=CLI 077434 0024

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2025-09-03

TÜV SÜD Product Service GmbH
Medical and Health Services

Chenchuan Weng

Chenchuan Weng (Sep 3, 2025 16:45:11 GMT+8)

Chenchuan Weng
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Dr. Mostafa Mahmoud

Dr. Mostafa Mahmoud (Sep 3, 2025 10:46:17 GMT+2)

Dr. Mostafa Mahmoud
Application Reviewer



Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
Chlamydia Rapid Test Cassette (Swab/Urine), Basic UDI-DI: 69340780CHL71A00JT	Class C for professional use	N/A	Certification as follows: V1 077434 0011 Rev. 02 NB: 0123
LH Ovulation Rapid Test Strip(Urine); LH Ovulation Rapid Test Cassette(Urine); LH Ovulation Rapid Test Midstream(Urine), Basic UDI-DI: 69340780LH11A00C3	Class B incl. PLU and ST	N/A	Certification as follows: V1 077434 0015 Rev. 03 NB: 0123
LH Ovulation Rapid Test Strip(Urine); LH Ovulation Rapid Test Cassette(Urine); LH Ovulation Rapid Test Midstream(Urine); Basic UDI-DI: 69340780LH11B00C8	Class B incl. PLU and ST	N/A	Certification as follows: V1 077434 0015 Rev. 03 NB: 0123
HCG Pregnancy Rapid Test Strip(Urine); HCG Pregnancy Rapid Test Cassette(Urine); HCG Pregnancy Rapid Test Midstream(Urine); Basic UDI-DI: 69340780HCG11A01F4	Class B incl. PLU and ST	N/A	Certification as follows: V1 077434 0015 Rev. 03 NB: 0123



<p>HCG Pregnancy Rapid Test Strip(Urine); HCG Pregnancy Rapid Test Cassette(Urine); HCG Pregnancy Rapid Test Midstream(Urine)</p> <p>Basic UDI-DI: 69340780HCG11C01FE</p>	Class B incl. PLU and ST	N/A	<p>Certification as follows: V1 077434 0015 Rev. 03 NB: 0123</p>
<p>Toxo IgG/IgM Rapid Test Cassette(Whole Blood/Serum/Plasma)</p> <p>Basic UDI-DI: 69340780TGM42A00TY</p>	Class C for professional use	<p>Identification of the corresponding device under IVDD: Toxo IgG/IgM Rapid Test Cassette (Serum/Plasma)</p>	<p>Certification as follows: V1 077434 0011 Rev. 02 NB: 0123</p>
<p>PSA Rapid Test Cassette(Whole Blood/Serum/Plasma)</p> <p>Basic UDI-DI: 69340780PSA42A00T4</p>	Class C for professional use	N/A	<p>Certification as follows: V1 077434 0011 Rev. 02 NB: 0123</p>
<p>FOB Rapid Test Cassette(Feces); FOB Rapid Test Strip(Feces)</p> <p>Basic UDI-DI: 69340780FOB61A01KY</p>	Class C incl. ST/NPT/CDx	N/A	<p>Certification as follows: V1 077434 0015 Rev. 03 NB: 0123</p>
<p>Bacterial Vaginosis PH Panel (Vaginal Discharge)</p> <p>Basic UDI-DI: 69340780VPH70A01YK</p>	Class C incl. ST/NPT/CDx	N/A	<p>Certification as follows: V1 077434 0015 Rev. 03 NB: 0123</p>
<p>Toxo IgM Rapid Test Cassette (Serum/Plasma)</p> <p>Basic UDI-DI: 69340780TXM31A004J</p>	Class C for professional use	N/A	<p>Certification as follows: V1 077434 0011 Rev. 02 NB: 0123</p>
<p>Rubella IgM Rapid Test Cassette (Serum/Plasma)</p> <p>Basic UDI-DI: 69340780RUM31A00ZN</p>	Class C for professional use	N/A	<p>Certification as follows: V1 077434 0011 Rev. 02 NB: 0123</p>



Rubella IgG Rapid Test Cassette (Serum/Plasma) Basic UDI-DI: 69340780RUG31A00X8	Class C for professional use	N/A	Certification as follows: V1 077434 0011 Rev. 02 NB: 0123
CMV IgM Rapid Test Cassette (Serum/Plasma) Basic UDI-DI: 69340780CMM31A00LH	Class C for professional use	N/A	Certification as follows: V1 077434 0011 Rev. 02 NB: 0123
CMV IgG Rapid Test Cassette (Serum/Plasma) Basic UDI-DI: 69340780CMG31A00J3	Class C for professional use	N/A	Certification as follows: V1 077434 0011 Rev. 02 NB: 0123
ToRCH (Toxo, Rubella, CMV, HSV) IgM Combo Rapid Test (Serum/Plasma) Basic UDI-DI: 69340780TMC34A00T7	Class C for professional use	N/A	Certification as follows: V1 077434 0011 Rev. 02 NB: 0123
HBsAg Rapid Test Cassette(Whole Blood /Serum /Plasma) Basic UDI-DI: 69340780HBSG41A002X	Class D for professional use	Identification of the corresponding device under IVDD: HBsAg Rapid Test Cassette(Serum /Plasma)	Certification as follows: 1434-IVDD-060/2022; 1434-IVDD-061/2022; NB: 1434 TÜV SÜD Product Service GmbH is responsible for appropriate surveillance starting from transfer date: 2025-09-26
HCV Ab Rapid Test Cassette Basic UDI-DI: 69340780HCVB41A0034	Class D incl. NPT and PLU	Identification of the corresponding device under IVDD: HCV Rapid Test Cassette(Serum /Plasma)	Certification as follows: 1434-IVDD-058/2022; 1434-IVDD-059/2022; NB: 1434 TÜV SÜD Product Service GmbH is responsible for appropriate surveillance starting from transfer date: 2025-09-26
HIV 1.2.O Rapid Test Cassette (Whole Blood/Serum/Plasma) Basic UDI-DI:	Class D for professional use	Identification of the corresponding device under IVDD:	Certification as follows: 1434-IVDD-063/2022; 1434-IVDD-064/2022; NB: 1434



69340780HIV42A00RK		Same device name and intended purpose, but using different conjugate particles for devices under IVDD and IVDR.	TÜV SÜD Product Service GmbH is responsible for appropriate surveillance starting from transfer date: 2025-09-26
COVID-19 Antigen Rapid Test Cassette(Nasal Swab) Basic UDI-DI: 69340780COVN81A00CV	Class D incl. PLU and ST	N/A	Certification as follows: 1434-IVDD-189/2022; NB: 1434 TÜV SÜD Product Service GmbH is responsible for appropriate surveillance starting from transfer date: 2025-09-26

Legend: ST – self-testing; NPT – near-patient testing; PLU – professional use laboratory device



Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
Syphilis Rapid Test Cassette(Whole Blood /Serum/Plasma); Syphilis Rapid Test Strip(Whole Blood /Serum/Plasma) Basic UDI-DI: 69340780SYP41A0062	Class C for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
hCG Pregnancy Rapid Test Strip(Serum/Plasma/Urine); hCG Pregnancy Rapid Test Cassette(Serum/Plasma/Urine) Basic UDI-DI: 69340780HCG21A00FD	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
hCG Pregnancy Rapid Test Strip(Serum/Plasma/Urine); hCG Pregnancy Rapid Test Cassette(Serum/Plasma/Urine) Basic UDI-DI: 69340780HCG21B00FJ	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
hCG Pregnancy Rapid Test Strip(Serum/Plasma/Urine); hCG Pregnancy Rapid Test Cassette(Serum/Plasma/Urine) Basic UDI-DI: 69340780HCG21C00FP	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
AMP Rapid Test Strip(Urine); AMP Rapid Test Cassette(Urine); AMP Rapid Test Panel(Urine); AMP Rapid Test Dip Card(Urine) Basic UDI-DI:	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives



69340780AMP11A00KU			
AMP Rapid Test Strip(Urine); AMP Rapid Test Cas- sette(Urine); AMP Rapid Test Panel(Urine); AMP Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780AMP11B00KZ	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
AMP Rapid Test Strip(Urine); AMP Rapid Test Cas- sette(Urine); AMP Rapid Test Panel(Urine); AMP Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780AMP11C00L6	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
BZO Rapid Test Strip(Urine); BZO Rapid Test Cas- sette(Urine); BZO Rapid Test Panel(Urine); BZO Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780BNZ11A00R2	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
BZO Rapid Test Strip(Urine); BZO Rapid Test Cas- sette(Urine); BZO Rapid Test Panel(Urine); BZO Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780BNZ11B00R7	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
BZO Rapid Test Strip(Urine); BZO Rapid Test Cas- sette(Urine); BZO Rapid Test Panel(Urine); BZO Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780BNZ11C00RC	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
BZO Rapid Test Strip(Urine); BZO Rapid Test Cas- sette(Urine); BZO Rapid Test Panel(Urine); BZO Rapid Test Dip Card(Urine)	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives



Basic UDI-DI: 69340780BNZ11D00RH			
COC Rapid Test Strip(Urine); COC Rapid Test Cas- sette(Urine); COC Rapid Test Panel(Urine); COC Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780COC11A00GT	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
COC Rapid Test Strip(Urine); COC Rapid Test Cas- sette(Urine); COC Rapid Test Panel(Urine); COC Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780COC11C00H5	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
COC Rapid Test Strip(Urine); COC Rapid Test Cas- sette(Urine); COC Rapid Test Panel(Urine); COC Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780COC11B00GY	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
THC Rapid Test Strip(Urine); THC Rapid Test Cas- sette(Urine); THC Rapid Test Panel(Urine); THC Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780THC11A00P7	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
THC Rapid Test Strip(Urine); THC Rapid Test Cas- sette(Urine); THC Rapid Test Panel(Urine); THC Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780THC11B00PC	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
THC Rapid Test Strip(Urine); THC Rapid Test Cas- sette(Urine); THC Rapid Test	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives



<p>Panel(Urine); THC Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780THC11C00PH</p>			
<p>MOP Rapid Test Strip(Urine); MOP Rapid Test Cas- sette(Urine); MOP Rapid Test Panel(Urine); MOP Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780MOP11A00U2</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
<p>MOP Rapid Test Strip(Urine); MOP Rapid Test Cas- sette(Urine); MOP Rapid Test Panel(Urine); MOP Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780MOP11B00U7</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
<p>MET Rapid Test Strip(Urine); MET Rapid Test Cas- sette(Urine); MET Rapid Test Panel(Urine); MET Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780MET11A00QC</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
<p>MET Rapid Test Strip(Urine); MET Rapid Test Cas- sette(Urine); MET Rapid Test Panel(Urine); MET Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780MET11B00QH</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
<p>MET Rapid Test Strip(Urine); MET Rapid Test Cas- sette(Urine); MET Rapid Test Panel(Urine); MET Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780MET11C00QN</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives



<p>FOB Rapid Test Cassette(Feces); FOB Rapid Test Strip(Feces)</p> <p>Basic UDI-DI: 69340780FOB61A00KW</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate under Directives</p>
<p>FOB Rapid Test Cassette(Feces); FOB Rapid Test Strip(Feces)</p> <p>Basic UDI-DI: 69340780FOB61B00L3</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate under Directives</p>
<p>FOB Rapid Test Cassette(Feces); FOB Rapid Test Strip(Feces)</p> <p>Basic UDI-DI: 69340780FOB61C00L8</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate under Directives</p>
<p>Whole C-reactive protein (CRP) Rapid Test Cassette(Fluorescence Immunochromatography)</p> <p>Basic UDI-DI: 69340780RFCRP41A00ZH</p>	<p>Class C for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate under Directives</p>
<p>hCG Pregnancy Rapid Test Strip(Urine); hCG Pregnancy Rapid Test Cassette(Urine)</p> <p>Basic UDI-DI: 69340780HCG11A00F2</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate under Directives</p>
<p>hCG Pregnancy Rapid Test Strip(Urine); hCG Pregnancy Rapid Test Cassette(Urine)</p> <p>Basic UDI-DI: 69340780HCG11B00F7</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate under Directives</p>
<p>hCG Pregnancy Rapid Test Strip(Urine); hCG Pregnancy Rapid Test Cassette(Urine)</p> <p>Basic UDI-DI: 69340780HCG11C00FC</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate under Directives</p>



<p>Syphilis Rapid Test Cas- sette(Serum/Plasma); Syphilis Rapid Test Strip(Serum/Plasma)</p> <p>Basic UDI-DI: 69340780SYP31A005P</p>	<p>Class C for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>
<p>Alcohol Rapid Test Strip(Urine); Alcohol Rapid Test Panel(Urine)</p> <p>Basic UDI-DI: 69340780ALC11A00E2</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>
<p>Alcohol Rapid Test Strip(Urine); Alcohol Rapid Test Panel(Urine)</p> <p>Basic UDI-DI: 69340780ALC11B00E7</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>
<p>BAR Rapid Test Strip(Urine); BAR Rapid Test Cas- sette(Urine); BAR Rapid Test Panel(Urine); BAR Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780BAR11A00EV</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>
<p>BAR Rapid Test Strip(Urine); BAR Rapid Test Cas- sette(Urine); BAR Rapid Test Panel(Urine); BAR Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780BAR11B00F2</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>
<p>BUP Rapid Test Strip(Urine); BUP Rapid Test Cas- sette(Urine); BUP Rapid Test Panel(Urine); BUP Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780BUP11A00QP</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>
<p>BUP Rapid Test Strip(Urine); BUP Rapid Test Cas- sette(Urine); BUP Rapid Test Panel(Urine); BUP Rapid Test Dip Card(Urine)</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>



Basic UDI-DI: 69340780BUP11B00QU			
COT Rapid Test Strip(Urine); COT Rapid Test Cas- sette(Urine); COT Rapid Test Panel(Urine); COT Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780COT11A00PQ	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
COT Rapid Test Strip(Urine); COT Rapid Test Cas- sette(Urine); COT Rapid Test Panel(Urine); COT Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780COT11B00PV	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
COT Rapid Test Strip(Urine); COT Rapid Test Cas- sette(Urine); COT Rapid Test Panel(Urine); COT Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780COT11C00Q2	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
COT Rapid Test Strip(Urine); COT Rapid Test Cas- sette(Urine); COT Rapid Test Panel(Urine); COT Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780COT11D00Q7	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
EDDP Rapid Test Strip(Urine); EDDP Rapid Test Cas- sette(Urine); EDDP Rapid Test Panel(Urine); EDDP Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780EDD11A00CK	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
EDDP Rapid Test Strip(Urine); EDDP Rapid Test Cas- sette(Urine); EDDP Rapid Test	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives



<p>Panel(Urine); EDDP Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780EDD11B00CQ</p>			
<p>Ethyl Glucuronide Rapid Test Strip(Urine); Ethyl Glucuronide Rapid Test Cassette(Urine); Ethyl Glucuronide Rapid Test Panel(Urine); Ethyl Glucuronide Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780ETG11A00NA</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
<p>Ethyl Glucuronide Rapid Test Strip(Urine); Ethyl Glucuronide Rapid Test Cassette(Urine); Ethyl Glucuronide Rapid Test Panel(Urine); Ethyl Glucuronide Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780ETG11B00NF</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
<p>FYL Rapid Test Strip(Urine); FYL Rapid Test Cassette(Urine); FYL Rapid Test Panel(Urine); FYL Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780FYL11A00TK</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
<p>FYL Rapid Test Strip(Urine); FYL Rapid Test Cassette(Urine); FYL Rapid Test Panel(Urine); FYL Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780FYL11B00TQ</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
<p>KET Rapid Test Strip(Urine); KET Rapid Test Cassette(Urine); KET Rapid Test Panel(Urine); KET Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780KET11A00P6</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives



<p>KET Rapid Test Strip(Urine); KET Rapid Test Cas- sette(Urine); KET Rapid Test Panel(Urine); KET Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780KET11B00PB</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
<p>6-MAM Rapid Test Strip(Urine); 6-MAM Rapid Test Cas- sette(Urine); 6-MAM Rapid Test Panel(Urine); 6-MAM Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780MAM11A00KD</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
<p>MDMA Rapid Test Strip(Urine); MDMA Rapid Test Cas- sette(Urine); MDMA Rapid Test Panel(Urine); MDMA Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780MDM11A00LY</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
<p>MDMA Rapid Test Strip(Urine); MDMA Rapid Test Cas- sette(Urine); MDMA Rapid Test Panel(Urine); MDMA Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780MDM11B00M5</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
<p>MDMA Rapid Test Strip(Urine); MDMA Rapid Test Cas- sette(Urine); MDMA Rapid Test Panel(Urine); MDMA Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780MDM11C00MA</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
<p>MDMA Rapid Test Strip(Urine); MDMA Rapid Test Cas- sette(Urine); MDMA Rapid Test Panel(Urine); MDMA Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI:</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives



69340780MDM11D00MF			
<p>MTD Rapid Test Strip(Urine); MTD Rapid Test Cas- sette(Urine); MTD Rapid Test Panel(Urine); MTD Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780MTH11A00TF</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
<p>MTD Rapid Test Strip(Urine); MTD Rapid Test Cas- sette(Urine); MTD Rapid Test Panel(Urine); MTD Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780MTH11B00TL</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
<p>OPI Rapid Test Strip(Urine); OPI Rapid Test Cassette(Urine); OPI Rapid Test Panel(Urine); OPI Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780OPI11A00SW</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
<p>OPI Rapid Test Strip(Urine); OPI Rapid Test Cassette(Urine); OPI Rapid Test Panel(Urine); OPI Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780OPI11B00T3</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
<p>PCP Rapid Test Strip(Urine); PCP Rapid Test Cas- sette(Urine); PCP Rapid Test Panel(Urine); PCP Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780PCP11A00PF</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
<p>PGB Rapid Test Strip(Urine); PGB Rapid Test Cas- sette(Urine); PGB Rapid Test Panel(Urine); PGB Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI:</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives



69340780PGB11A00KV			
<p>PGB Rapid Test Strip(Urine); PGB Rapid Test Cas- sette(Urine); PGB Rapid Test Panel(Urine); PGB Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780PGB11B00L2</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
<p>PGB Rapid Test Strip(Urine); PGB Rapid Test Cas- sette(Urine); PGB Rapid Test Panel(Urine); PGB Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780PGB11C00L7</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
<p>Synthetic Marijuana (K2) Rapid Test Strip(Urine); Synthetic Mari- juana (K2) Rapid Test Cas- sette(Urine); Synthetic Marijuana (K2) Rapid Test Panel(Urine); Synthetic Marijuana (K2) Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780SMA11A00QF</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
<p>Synthetic Marijuana (K2) Rapid Test Strip(Urine); Synthetic Mari- juana (K2) Rapid Test Cas- sette(Urine); Synthetic Marijuana (K2) Rapid Test Panel(Urine); Synthetic Marijuana (K2) Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780SMA11C00QR</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
<p>Synthetic Marijuana K2+(AB-Pi- naca) Rapid Test Strip(Urine); Synthetic Marijuana K2+(AB-Pi- naca) Rapid Test Cas- sette(Urine); Synthetic Marijuana K2+(AB-Pinaca) Rapid Test Pa- nel(Urine); Synthetic Marijuana K2+(AB-Pinaca) Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI:</p>	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives



69340780SMP11A00WJ			
TCA Rapid Test Strip(Urine); TCA Rapid Test Cas- sette(Urine); TCA Rapid Test Panel(Urine); TCA Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780TCA11A00KQ	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
TCA Rapid Test Strip(Urine); TCA Rapid Test Cas- sette(Urine); TCA Rapid Test Panel(Urine); TCA Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780TCA11B00KV	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
TML Rapid Test Strip(Urine); TML Rapid Test Cas- sette(Urine); TML Rapid Test Panel(Urine); TML Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780TML11A00VH	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
TML Rapid Test Strip(Urine); TML Rapid Test Cas- sette(Urine); TML Rapid Test Panel(Urine); TML Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780TML11C00VT	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
Adulteration Test Strip(Urine) Basic UDI-DI: 69340780ADT16A00HS	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives
GAB Rapid Test Strip(Urine); GAB Rapid Test Cas- sette(Urine); GAB Rapid Test Panel(Urine); GAB Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780GAB11A00BC	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate un- der Directives



<p>KRA Rapid Test Strip(Urine); KRA Rapid Test Cas- sette(Urine); KRA Rapid Test Panel(Urine); KRA Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780KRA11A00NC</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>
<p>LSD Rapid Test Strip(Urine); LSD Rapid Test Cas- sette(Urine); LSD Rapid Test Panel(Urine); LSD Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780LSD11A00QP</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>
<p>MDPV Rapid Test Strip(Urine); MDPV Rapid Test Cas- sette(Urine); MDPV Rapid Test Panel(Urine); MDPV Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780MDP11A00N7</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>
<p>MEP Rapid Test Strip(Urine); MEP Rapid Test Cas- sette(Urine); MEP Rapid Test Panel(Urine); MEP Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780MEP11A00NQ</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>
<p>MPD Rapid Test Strip(Urine); MPD Rapid Test Cas- sette(Urine); MPD Rapid Test Panel(Urine); MPD Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780MPD11A00PP</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>
<p>MPD Rapid Test Strip(Urine); MPD Rapid Test Cas- sette(Urine); MPD Rapid Test Panel(Urine);</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>



MPD Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780MPD11B00PU			
MQL Rapid Test Strip(Urine); MQL Rapid Test Cas- sette(Urine); MQL Rapid Test Panel(Urine); MQL Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780MQL11A00TG	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
OXY Rapid Test Strip(Urine); OXY Rapid Test Cas- sette(Urine); OXY Rapid Test Panel(Urine); OXY Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780OXY11A005R	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
PPX Rapid Test Strip(Urine); PPX Rapid Test Cas- sette(Urine); PPX Rapid Test Panel(Urine); PPX Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780PPX11A00ZL	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
THC Rapid Test Strip(Urine); THC Rapid Test Cas- sette(Urine); THC Rapid Test Panel(Urine); THC Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780THC11D00PN	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
UR-144 Rapid Test Strip(Urine); UR-144 Rapid Test Cas- sette(Urine); UR-144 Rapid Test Panel(Urine); UR-144 Rapid Test Dip Card(Urine) Basic UDI-DI: 69340780UR14411A007C	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives



<p>ZOL Rapid Test Strip(Urine); ZOL Rapid Test Cas- sette(Urine); ZOL Rapid Test Panel(Urine); ZOL Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780ZOL11A0028</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>
<p>ZOP Rapid Test Strip(Urine); ZOP Rapid Test Cas- sette(Urine); ZOP Rapid Test Panel(Urine); ZOP Rapid Test Dip Card(Urine)</p> <p>Basic UDI-DI: 69340780ZOP11A003U</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>
<p>Multi-Drug Rapid Test Cas- sette(Urine); Multi-Drug Rapid Test Panel(Urine); Multi-Drug Rapid Test Dip Card(Urine); Multi-Drug Rapid Test Cup(Urine)</p> <p>Basic UDI-DI: 69340780MDR1XA00XB</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>
<p>ALC Rapid Test Strip(Oral Fluid)</p> <p>Basic UDI-DI: 69340780ALC81A00GF</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>
<p>AMP Rapid Test Cassette(Oral Fluid)</p> <p>Basic UDI-DI: 69340780AMP81A00N9</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>
<p>AMP Rapid Test Cassette(Oral Fluid)</p> <p>Basic UDI-DI: 69340780AMP81B00NE</p>	<p>Class B for professional use</p>	<p>N/A</p>	<p>N/A - Device did not require a Notified Body certificate un- der Directives</p>



BAR Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780BAR81A00HA	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
BUP Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780BUP81A00T4	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
BUP Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780BUP81B00T9	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
BZO Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780BNZ81A00TF	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
BZO Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780BNZ81B00TL	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
COC Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780COC81A00K8	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
COC Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780COC81B00KD	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
COC Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780COC81C00KJ	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives



COT Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780COT81A00S5	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
FYL Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780FYL81A00VY	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
FYL Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780FYL81B00W5	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
KET Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780KET81A00RK	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
KET Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780KET81B00RQ	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
MDMA Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780MDM81A00PD	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
MET Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780MET81A00SR	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
MET Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780MET81B00SW	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives



MOP Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780MOP81A00WF	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
MOP Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780MOP81B00WL	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
MOP Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780MOP81C00WR	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
MOP Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780MOP81D00WW	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
MTD Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780MTH81A00VU	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
OXY Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780OXY81A0086	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
PCP Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780PCP81A00RU	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
PCP Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780PCP81B00RZ	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives



Synthetic Marijuana (K2) Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780SMA81A00SU	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
Synthetic Marijuana K2+(AB-Pinaca) Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780SMP81A00YX	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
THC Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780THC81A00RL	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
THC Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780THC81B00RR	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
THC Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780THC81C00RW	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
TML Rapid Test Cassette(Oral Fluid) Basic UDI-DI: 69340780TML81A00XW	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
Multi-Drug Rapid Test Cassette(Oral Fluid); Multi-Drug Rapid Test Cup(Oral Fluid); Multi-Drug Rapid Test Mid-stream(Oral Fluid) Basic UDI-DI: 69340780MDR8XA00ZQ	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives



Dengue Rapid Test Cassette(Whole Blood/Serum/Plasma) Basic UDI-DI: 69340780DEN42A00HT	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
Dengue NS1 Antigen Rapid Test Cassette(Whole Blood/Serum/Plasma) Basic UDI-DI: 69340780DEG41A00ER	Class C for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
Dengue Ag and Ab Combo Rapid Test Cassette(Whole Blood/Serum/Plasma) Basic UDI-DI: 69340780DGC43A00EM	Class C for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
CRP Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) Basic UDI-DI: 69340780CRP43A00R6	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
Malaria P.f./Pan Rapid Test Cassette(Whole Blood) Basic UDI-DI: 69340780MPN52A00VC	Class C incl. NPT and PLU	N/A	N/A - Device did not require a Notified Body certificate under Directives
Malaria P.f./P.v. Rapid Test Cassette(Whole Blood) Basic UDI-DI: 69340780MPV52A00YL	Class C incl. NPT and PLU	N/A	N/A - Device did not require a Notified Body certificate under Directives
Strep A Rapid Test Cassette(Throat Swab); Strep A Rapid Test Strip(Throat Swab) Basic UDI-DI: 69340780STA81A00WK	Class C incl. NPT, PLU and ST	Identification of the corresponding device under IVDD: Same device name, but for professional use under IVDD.	N/A - Device did not require a Notified Body certificate under Directives



COVID-19 + Flu A&B + RSV Antigen Combo Rapid Test Cassette (Nasal Swab) Basic UDI-DI: 69340780CFRN84A0063	Class D incl. PLU and ST	Identification of the corresponding device under IVDD: Same device name, but for professional use under IVDD.	N/A - Device did not require a Notified Body certificate under Directives
COVID-19 + Flu A&B + RSV Antigen Combo Rapid Test Cassette (Nasopharyngeal Swab) Basic UDI-DI: 69340780RCF84A00PM	Class D incl. PLU and NPT	N/A	N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2025-02-17	713266154; 713331341; SH24708A01; SH24708A02; SH24708A03; SH24708A04; SH24708A05; SH24708A06; SH24708A07; SH24708A08; SH24708A12; SH24708A13; SH25708A01; SH25708A02	Initial issue
2025-09-03	SH25070821_CLI SH2470800_CLI_transfer	Rev.01 Addition of 8 devices to Table 1: 69340780FOB61A01KY, 69340780VPH70A01YK, 69340780TXM31A004J, 69340780RUM31A00ZN, 69340780RUG31A00X8, 69340780CMM31A00LH, 69340780CMG31A00J3, 69340780TMC34A00T7 Transfer of 4 devices from table 2 to table 1: 69340780HBSG41A002X 69340780HCVB41A0034 69340780HIV42A00RK 69340780COVN81A00CV Addition of transfer date for these devices.