Genome Identification Diagnostics GmbH
Ebinger Straße 4
72479 Straßberg
Germany

Notified Body Confirmation Letter

Registration no.: D1441400008

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) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain in vitro diagnostic medical devices

This letter confirms that mdc medical device certification GmbH (Kriegerstr. 6, 70191 Stuttgart, Germany), a Notified Body (NB) designated against Regulation (EU) 2017/746 (IVDR) and identified by the number 0483 on NANDO, has 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 following manufacturer:

Genome Identification Diagnostics GmbH
Ebinger Straße 4
72479 Straßberg
Germany

SRN: DE-MF-000026887

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 the NB is also responsible for appropriate surveillance of the corresponding devices under Directive 98/79/EC. Table 2 identifies the devices for which an IVDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under Directive 98/79/EC.

In the case of 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issued under Directive 98/79/EC (IVDD) that expired after 26 May 2022 and before 09 July 2024, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under IVDR by the date of IVDD certificate expiry; or provided evidence that a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, by 09 July 2024 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 110.3b of IVDR (as amended by Regulation (EU) 2024/1860), are shown below:

- 31 December 2027 for devices covered by an IVDD certificate regardless of their risk class under the IVDR
- For devices not requiring the involvement of a notified body under the IVDD, but requiring it under the IVDR and for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with Directive 98/79/EC, the following dates apply:
  - 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

Stuttgart, 2025-07-18

Head of Notified Body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under Directive 98/79/EC:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Sexually Transmitted Pathogens Kit (RDB 2110 / RDB 2110 X) **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: STD Reverse Hybridization Kit (RDB 2110 / RDB 2110 X) and STD Amplification mix (RDB 2111 / RDB 2111 X	D1441400006; NB 0483
Chlamydia trachomatis Detection Kit (RDB 2117 / RDB 2117 X) **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: Chlamydia trachomatis Reverse Hybridization Kit (RDB 2117 / RDB 2117 X) and Chlamydia trachomatis Amplification mix (RDB 2118 / RDB 2118 X)	D1441400006; NB 0483
Respiratory Pathogens Bacterial Kit (RDB 2135 / RDB 2135 X) **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: CAP Bac Reverse Hybridization Kit (RDB 2135 / RDB 2135 X) and CAP Bac Amplification mix (RDB 2136 / RDB 2136 X)	D1441400006; NB 0483
Sexually Transmitted Pathogens Bacterial Kit (RDB 2335 / RDB 2335 X) **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: STI Reverse Hybridization kit (RDB2335, RDB2335X) and STI Amplification mix (RDB2336, RDB2336X)	D1441400006; NB 0483
CMVSpot Interferon-γ (ELSP 5530) **(EliSpot Kit enzymatic)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	CMVSpot Interferon- γ (ELSP5530)	D1441400006; NB 0483

Table 2: Devices covered by this letter and for which the NB 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 at the pre-application stage)	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
HPV Typing Kit **(RDB 2270 / RDB 2270 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: HPV Easy-Typing Reverser Hybridisierungskit (RDB 2270 / RDB 2270 X) and HPV Easy Amplifikations-Mix (RDB 2271 / RDB 2271 X)	N/A - Device did not require a Notified Body certificate under Directives
HPV Detection Kit **(RDB 2272 / RDB 2272 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: HPV Easy-Screening Reverser Hybridisierungskit (RDB 2272 / RDB 2272 X) and HPV Easy Amplifikations-Mix (RDB 2271 / RDB 2271 X)	N/A - Device did not require a Notified Body certificate under Directives
Respiratory Pathogens Viral Kit **(RDB 2355 / RDB 2355 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: CAP Vir Reverser Hybridisierungskit (RDB 2355 / RDB 2355 X) and CAP Vir Amplifikations-Mix (RDB 2356 / RDB 2356 X)	N/A - Device did not require a Notified Body certificate under Directives
Celiac Disease Risk Kit (RDB 2105 / RDB 2105 X) **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: Zöliakie / Celiac disease Reverser Hybridisierungskit (RDB 2105 / RDB 2105 X) and Zöliakie Amplifikations-Mix (RDB 2106 / RDB 2106 X)	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Lactose Intolerance Risk Kit **(RDB 2120 / RDB 2120 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: Lactose Intoleranz Reverser Hybridisierungskit (RDB 2120 / RDB 2120 X) and Lactose Intoleranz Amplifikations-Mix (RDB 2121 / RDB 2121 X)	N/A - Device did not require a Notified Body certificate under Directives
Fructose Intolerance Risk Kit **(RDB 2175 / RDB 2175 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: Hereditäre Fructose Intoleranz (HFI): Mutationen im Aldolase B Gen Reverser Hybridisierungskit (RDB 2175 / RDB 2175 X) and Hereditäre Fructose Intoleranz (HFI) Amplifikations-Mix (RDB 2176 / RDB 2176 X)	N/A - Device did not require a Notified Body certificate under Directives
Shared Epitope Detection Kit **(RDB 2035 / RDB 2035 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: HLA-DRB1 Shared Epitope QKRAA/QRRAA/RRRAA Reverser Hybridisierungskit (RDB 2035 / RDB 2035 X) and HLA-DRB1 Shared Epitope QKRAA/QRRAA/RRRAA Amplifikations-Mix (RDB 2036 / RDB 2036 X)	N/A - Device did not require a Notified Body certificate under Directives
Apolipoprotein E + B Typing Kit **(RDB 2050 / RDB 2050 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: Apolipoprotein E + B Reverser Hybridisierungskit (RDB 2050 / RDB 2050 X) and Apolipoprotein E + B Amplifikations-Mix (RDB 2051 / RDB 2051 X)	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Osteoporosis Risk Factor Kit **(RDB 2055 / RDB 2055 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: Genetische Osteoporose-Risikofaktoren: Collagen Typ I α1 S/s- und Vitamin D Rezeptor B/b-Allele Reverser Hybridisierungskit (RDB 2055 / RDB 2055 X) and Genetische Osteoporose Risikofaktoren Amplifikations-Mix (RDB 2056 / RDB 2056 X)	N/A - Device did not require a Notified Body certificate under Directives
HLA-B*27 Detection Kit **(RDB 2300 / RDB 2300 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: HLA-B*27 Reverser Hybridisierungskit (RDB 2300 / RDB 2300 X) and HLA-B*27 Amplifikations-Mix (RDB 2301 / RDB 2301 X)	N/A - Device did not require a Notified Body certificate under Directives
CVD Risk Panel Kit **(RDB 2210 / RDB 2210 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: CVD Panel Reverser Hybridisierungskit (RDB 2210 / RDB 2210 X) and CVD Panel Amplifikations-Mix (RDB 2211 / RDB 2211 X)	N/A - Device did not require a Notified Body certificate under Directives
Coumarin Tolerance Kit **(RDB 2075 / RDB 2075 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: Cumarin Panel Coumarin Panel Reverser Hybridisierungskit (RDB 2075 / RDB 2075 X) and Cumarin Panel Amplifikations-Mix (RDB 2076 / RDB 2076 X)	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Glutathione-S Transferase Typing Kit **(RDB 2090 / RDB 2090 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: GST Reverser Hybridisierungskit (RDB 2090 / RDB 2090 X) and Glutathion-S-Transferase M1, T1 und P1 Amplifikations-Mix (RDB 2091 / RDB 2091 X)	N/A - Device did not require a Notified Body certificate under Directives
CYP2D6 Typing Kit **(RDB 2310 / RDB 2310 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: Zytochrom P450: CYP2D6 Reverser Hybridisierungskit (RDB 2310 / RDB 2310 X) and Zytochrom P450: CYP2D6 Amplifikations-Mix (RDB 2311 / RDB 2311 X)	N/A - Device did not require a Notified Body certificate under Directives
Statine Tolerance Kit **(RDB 2280 / RDB 2280 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: Statin-Toleranz Statin-Tolerance Reverser Hybridisierungskit (RDB 2280 / RDB 2280 X) and Statin-Toleranz Amplification-Mix (RDB 2281 / RDB 2281 X)	N/A - Device did not require a Notified Body certificate under Directives
BRAF Mutation Detection Kit **(RDB 2265 / RDB 2265 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: BRAF Reverser Hybridisierungskit (RDB 2265 / RDB 2265 X) and BRAF Amplifikation-Mix (RDB 2266 / RDB 2266 X)	N/A - Device did not require a Notified Body certificate under Directives
NRAS Mutation Detection Kit **(RDB 2285 / RDB 2285 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: NRAS Reverser Hybridisierungskit (RDB 2285 / RDB 2285 X) and NRAS Amplifikations-Mix (RDB 2286 / RDB 2286 X)	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
KRAS Mutation Detection Kit **(RDB 2295 / RDB 2295 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: KRAS Reverser Hybridisierungskit (RDB 2295 / RDB 2295 X) and KRAS Amplifikation-Mix (RDB 2296 / RDB 2296 X)	N/A - Device did not require a Notified Body certificate under Directives
Mycobacteria Detection Kit **(RDB 2255 / RDB 2255 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: Myco-Screen Reverser Hybridisierungskit (RDB 2255 / RDB 2255 X) and Myco-Screen Amplifikations-Mix (RDB 2256 / RDB 2256 X)	N/A - Device did not require a Notified Body certificate under Directives
AMR ESBL Risk Kit **(RDB 2180 / RDB 2180 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: ESBL Reverser Hybridisierungskit (RDB 2180 / RDB 2180 X) and ESBL Amplifikations-Mix (RDB 2181 / RDB 2181 X)	N/A - Device did not require a Notified Body certificate under Directives
AMR Carbapenemase Risk Kit **(RDB 2290 / RDB 2290 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: Carbapenemase Reverser Hybridisierungskit (RDB 2290 / RDB 2290 X) and (RDB 2290 / RDB 2290 X) Carbapenemase Amplifikations-Mix (RDB 2291 / RDB 2291 X)	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Periodontitis Risk Panel Kit **(RDB 2040 / RDB 2040 X)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: ParodontitisPlus PeriodontitisPlus Reverser Hybridisierungskit (RDB 2040 / RDB 2040 X) and ParodontitisPlus Amplifikations-Mix (RDB 2041 / RDB 2041 X)	N/A - Device did not require a Notified Body certificate under Directives
EBVSpot Interferon-ϒ **(ELSP 5520)** **(EliSpot Kit enzymatic)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	EBVSpot Interferon-ϒ (ELSP 5520)	N/A - Device did not require a Notified Body certificate under Directives
VZVSpot Interferon-ϒ **(ELSP 5590)** **(EliSpot Kit enzymatic)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	VZVSpot Interferon-ϒ (ELSP 5590)	N/A - Device did not require a Notified Body certificate under Directives
LymeSpot Interferon-ϒ **(ELSP 5510)** **(EliSpot Kit enzymatic)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	LymeSpot Interferon-ϒ (ELSP 5510)	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
TB Spot Interferon-ϒ **(ELSP 5540)** **(EliSpot Kit enzymatic)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	TB Spot Interferon-ϒ (ELSP 5540)	N/A - Device did not require a Notified Body certificate under Directives
NTM Spot Interferon-ϒ **(ELSP 5570)** **(EliSpot Kit enzymatic)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	NTM Spot Interferon-ϒ (ELSP 5570)	N/A - Device did not require a Notified Body certificate under Directives
CoV-*i*Spot Interferon-ϒ + Interleukin-2 **(ELSP 7010)** **(EliSpot Kit Fluorescence strip format)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	CoV-*i*Spot Interferon-ϒ + Interleukin-2 (ELSP 7010)	N/A - Device did not require a Notified Body certificate under Directives
CoV-*i*Spot Interferon-ϒ + Interleukin-2 **(ELSP 7020 / ELSP 7020 X)** **(EliSpot Kit Fluorescence)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	CoV-*i*Spot Interferon-ϒ + Interleukin-2 (ELSP 7020 / ELSP 7020 X)	N/A - Device did not require a Notified Body certificate under Directives
CoV-*i*Spot pure Interferon-ϒ + Interleukin-2 **(ELSP 7030)** **(EliSpot Kit Fluorescence strip format)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	CoV-*i*Spot pure Interferon-ϒ + Interleukin-2 (ELSP 7030)	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
CoV-*i*Spot pure Interferon-ϒ + Interleukin-2 **(ELSP 7040)** **(EliSpot Kit Fluorescence)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	CoV-*i*Spot pure Interferon-ϒ + Interleukin-2 (ELSP 7040)	N/A - Device did not require a Notified Body certificate under Directives
Varizella-*i*Spot Interferon-ϒ + Interleukin-2 **(ELSP 7090)** **(EliSpot Kit Fluorescence)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Varizella-*i*Spot Interferon-ϒ + Interleukin-2 (ELSP 7090)	N/A - Device did not require a Notified Body certificate under Directives
Borrelia-*i*Spot Interferon-ϒ + Interleukin-2 **(ELSP 7050)** **(EliSpot Kit Fluorescence)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Borrelia-*i*Spot Interferon-ϒ + Interleukin-2 (ELSP 7050)	N/A - Device did not require a Notified Body certificate under Directives
Borrelia-*i*Spot Interferon-ϒ + Interleukin-2 **(ELSP 7060)** **(EliSpot Kit Fluorescence strip format)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Borrelia-*i*Spot Interferon-ϒ + Interleukin-2 (ELSP 7060)	N/A - Device did not require a Notified Body certificate under Directives
NTM-*i*Spot Interferon-ϒ + Interleukin-2 **(ELSP 7070)** **(EliSpot Kit Fluorescence)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	NTM-*i*Spot Interferon-ϒ + Interleukin-2 (ELSP 7070)	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
NTM-*i*Spot Interferon-ɤ + Interleukin-2 **(ELSP 7080)** **(EliSpot Kit Fluorescence strip format)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	NTM-*i*Spot Interferon-ɤ + Interleukin-2 (ELSP 7080)	N/A - Device did not require a Notified Body certificate under Directives
EliSpot Interferon-ɤ **(ELSP 5000 / ELSP 5000 X)** **(EliSpot Basic Kit enzymatic)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	EliSpot Interferon-y Basis-Kit (ELSP 5000 / ELSP 5000 X)	N/A - Device did not require a Notified Body certificate under Directives
EliSpot Interferon-ɤ **(ELSP 5500 / ELSP 5500 X)** **(EliSpot Basic Kit enzymatic strip format)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	EliSpot Interferon-ɤ Basis-Kit (ELSP 5500 / ELSP 5500 X)	N/A - Device did not require a Notified Body certificate under Directives
EliSpot Interleukin-2 **(ELSP 5050)** **(EliSpot Basic Kit enzymatic)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	EliSpot Interleukin-2 (ELSP 5050)	N/A - Device did not require a Notified Body certificate under Directives
EliSpot Interleukin-2 **(ELSP 5650)** **(EliSpot Basic Kit enzymatic strip format)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	EliSpot Interleukin-2 (ELSP 5650)	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
EliSpot Interleukin-4 **(ELSP 5060)** **(EliSpot Basic Kit enzymatic)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	EliSpot Interleukin-4 (ELSP 5060)	N/A - Device did not require a Notified Body certificate under Directives
EliSpot Interleukin-4 **(ELSP 5660)** **(EliSpot Basic Kit enzymatic strip format)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	EliSpot Interleukin-4 (ELSP 5660)	N/A - Device did not require a Notified Body certificate under Directives
EliSpot Interleukin-5 **(ELSP 5010)** **(EliSpot Basic Kit enzymatic)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	EliSpot Interleukin-5 (ELSP 5010)	N/A - Device did not require a Notified Body certificate under Directives
EliSpot Interleukin-5 **(ELSP 5610)** **(EliSpot Basic Kit enzymatic strip format)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	EliSpot Interleukin-5 (ELSP 5610)	N/A - Device did not require a Notified Body certificate under Directives
EliSpot Interleukin-10 **(ELSP 5040)** **(EliSpot Basic Kit enzymatic)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	EliSpot Interleukin-10 (ELSP 5040)	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
EliSpot Interleukin-10 **(ELSP 5400)** **(EliSpot Basic Kit enzymatic strip format)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	EliSpot Interleukin-10 (ELSP 5400)	N/A - Device did not require a Notified Body certificate under Directives
EliSpot Interleukin-17A **(ELSP 5082)** **(EliSpot Basic Kit enzymatic)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	EliSpot Interleukin-17 (ELSP 5082)	N/A - Device did not require a Notified Body certificate under Directives
EliSpot Interleukin-17A **(ELSP 5682)** **(EliSpot Basic Kit enzymatic strip format)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	EliSpot Interleukin-17 (ELSP 5682)	N/A - Device did not require a Notified Body certificate under Directives
***i*-Spot Interferon-ɤ + Interleukin-17A** **(ELSP 5730)** **(EliSpot Basic Kit Fluorescence)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	*i*-Spot Assay-Kit Interferon-ɤ + Interleukin-17A (ELSP 5730)	N/A - Device did not require a Notified Body certificate under Directives
***i*-Spot Interferon-ɤ + Interleukin-17A** **(ELSP 5830)** **(EliSpot Basic Kit Fluorescence strip format)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	*i*-Spot Assay-Kit Interferon-ɤ + Interleukin-17A (ELSP 5830)	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
***i*-Spot Interferon-ϒ + Interleukin-2** **(ELSP 5710)** **(EliSpot Basic Kit Fluorescence)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	*i*-Spot Interferon-ϒ + Interleukin-2 (ELSP 5710)	N/A - Device did not require a Notified Body certificate under Directives
***i*-Spot Interferon-ϒ + Interleukin-2** **(ELSP 5810)** **(EliSpot Basic Kit Fluorescence strip format)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	*i*-Spot Interferon-ϒ + Interleukin-2 (ELSP 5810)	N/A - Device did not require a Notified Body certificate under Directives
***i*-Spot Interferon-ϒ + Interleukin-5** **(ELSP 5720)** **(EliSpot Basic Kit Fluorescence)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	*i*-Spot Interferon-ϒ + Interleukin-5 (ELSP 5720)	N/A - Device did not require a Notified Body certificate under Directives
***i*-Spot Interferon-ϒ + Interleukin-5** **(ELSP 5820)** **(EliSpot Basic Kit Fluorescence strip format)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	*i*-Spot Interferon-ϒ + Interleukin-5 (ELSP 5820)	N/A - Device did not require a Notified Body certificate under Directives
***i*-Spot Interferon-ϒ + Interleukin-2 + Interleukin-17A** **(ELSP 6000)** **(EliSpot Basic Kit Fluorescence)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	*i*-Spot Interferon-ϒ + Interleukin-2 + Interleukin-17A (ELSP 6000)	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
***i*-Spot Interferon-ϒ + Interleukin-2 + Interleukin-17A** **(ELSP 6100)** **(EliSpot Basic Kit Fluorescence strip format)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	*i*-Spot Interferon-ϒ + Interleukin-2 + Interleukin-17A (ELSP 6100)	N/A - Device did not require a Notified Body certificate under Directives
***i*-Spot Interferon-ϒ + Interleukin-2 + Interleukin-5** **(ELSP 6010)** **(EliSpot Basic Kit Fluorescence)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	*i*-Spot Interferon-ϒ + Interleukin-2 + Interleukin-5 (ELSP 6010)	N/A - Device did not require a Notified Body certificate under Directives
***i*-Spot Interferon-ϒ + Interleukin-2 + Interleukin-5** **(ELSP 6110)** **(EliSpot Basic Kit Fluorescence strip format)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	*i*-Spot Interferon-ϒ + Interleukin-2 + Interleukin-5 (ELSP 6110)	N/A - Device did not require a Notified Body certificate under Directives
***i*-Spot Interferon-ϒ + Interleukin-2 + Interleukin-6** **(ELSP 6040)** **(EliSpot Basic Kit Fluorescence)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	*i*-Spot Interferon-ϒ + Interleukin-2 + Interleukin-6 (ELSP 6040)	N/A - Device did not require a Notified Body certificate under Directives
***i*-Spot Interferon-ϒ + Interleukin-2 + Interleukin-6** **(ELSP 6140)** **(EliSpot Basic Kit Fluorescence strip format)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	*i*-Spot Interferon-ϒ + Interleukin-2 + Interleukin-6 (ELSP 6140)	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
HPV DNA-Array **(DA 4270)** **(Amplification mix with Reverse Hybridization Kit)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☒ Class C product ☐ for self-testing ☐ for use in near-patient tests ☐ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	Currently consisting of two separate products: HPV DNA-Array Reverser Hybridisierungskit (DA 4270) and HPV DNA-Array (DA 4271) Amplifikationsmix	N/A - Device did not require a Notified Body certificate under Directives
Borrelia burgdorferi IgG/IgM ImmunoArray **(IA 3010)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☐ Class C product ☐ for self-testing ☐ for use in near-patient tests ☒ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	*Borrelia burgdorferi* IgG/IgM ImmunoArray (IA 3010)	N/A - Device did not require a Notified Body certificate under Directives
EBV IgG/IgM ImmunoArray **(IA 3030)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☐ Class C product ☐ for self-testing ☐ for use in near-patient tests ☒ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	EBV IgG/IgM ImmunoArray (IA 3030)	N/A - Device did not require a Notified Body certificate under Directives
ANA IgG ImmunoArray **(IA 3000)**	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests ☐ Class C product ☐ for self-testing ☐ for use in near-patient tests ☒ Class B product ☐ for self-testing ☐ for use in near-patient tests ☐ Class $A_{sterile}$ product	ANA IgG ImmunoArray (IA 3000)	N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2025-07-18	D1441400008	Initial