ravo Diagnostika GmbH
Oltmannsstraße 5
79100 Freiburg
Germany

Notified Body Confirmation Letter

Registration no.: D1052800019

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:

ravo Diagnostika GmbH
Oltmannsstraße 5
79100 Freiburg
Germany

SRN: DE-MF-000024780

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issued under Directive 98/79/EC (IVDD) that expired after 26 May 2022 and before 09 July 2024, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under IVDR by the date of IVDD certificate expiry; or provided evidence that a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, 2026-07-17

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
N/A	☐ 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	N/A	N/A

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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
ravo PNS Blot **426073717PNSLINEASSAYKK**	☐ 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	N/A	N/A
ravo PNS 11 Line Assay **426073717PNSLINEASSAYKK**	☐ 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	N/A	N/A

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
ravo PNS 14 Line Assay **426073717PNSLINEASSAYKK**	☐ 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	N/A	N/A
ravo PNS 15 Line Assay **426073717PNSLINEASSAYKK**	☐ 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	N/A	N/A
ravo SOX1/Titin Line Assay **426073717PNSLINEASSAYKK**	☐ 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	N/A	N/A
ravo PCA-2 Line Assay **426073717PNSLINEASSAYKK**	☐ 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	N/A	N/A
ravo PCA-1 (Yo) Line Assay **426073717PNSLINEASSAYKK**	☐ 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	N/A	N/A

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
ravo Purkinje Line Assay **426073717PNSLINEASSAYKK**	☐ 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	N/A	N/A
ravo PNS9 DIVER **426073717PNSDIVERASSAYT3**	☐ 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	N/A	N/A
ravo PNS11 DIVER **426073717PNSDIVERASSAYT3**	☐ 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	N/A	N/A
ravo PNS14 DIVER **426073717PNSDIVERASSAYT3**	☐ 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	N/A	N/A
ravo PNS15 DIVER **426073717PNSDIVERASSAYT3**	☐ 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	N/A	N/A

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
ravo Purkinje DIVER **426073717PNSDIVERASSAYT3**	☐ 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	N/A	N/A
Hemkit Aspergillus IHA **426073717HEMKITASPIHAY2**	☐ 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	N/A	N/A
Hemkit Candida IHA **426073717HEMKITCALBIHATC**	☐ 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	N/A	N/A
Hemkit Lyme IHA **426073717HEMKITLYMEIHAAY**	☐ 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	N/A	N/A
Hemkit Leptospiren IHA **426073717HEMKITLEPTOIHAJX**	☐ 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	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2026-07-17	D1052800019	Rev01: Cancellation of products
2025-05-19	D1052800017	Initial

mdc medical device certification GmbH
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