Roboscreen GmbH
Hohmannstraße 7
04129 Leipzig
Germany

Notified Body Confirmation Letter

Registration no.: D1152500052

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:

Roboscreen GmbH
Hohmannstraße 7
04129 Leipzig
Germany

SRN: DE-MF-000024661

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issued under Directive 98/79/EC (IVDD) that expired after 26 May 2022 and before 09 July 2024, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under IVDR by the date of IVDD certificate expiry; or provided evidence that a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

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Date: 2025.05.15 19:13:01 EEST
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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, 2025-04-15

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
RoboGene HBV DNA Quantification Kit 3.1	☒ Class D product ☐ for self-testing ☐ for use in near-patient tests	RoboGene HBV DNA Quantification Kit 3.0	D1152500044 D1152500046 NB# 0483
RoboGene HCV RNA Quantification Kit 3.1	☒ Class D product ☐ for self-testing ☐ for use in near-patient tests	RoboGene HCV RNA Quantification Kit 3.0	D1152500044 D1152500043 NB# 0483
RoboGene HDV RNA Quantification Kit 3.0	☒ Class D product ☐ for self-testing ☐ for use in near-patient tests	RoboGene HDV RNA Quantification Kit 2.0	D1152500044 D1152500047 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
N/A	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests	N/A	N/A
	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests		
	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests		
	☐ Class D product ☐ for self-testing ☐ for use in near-patient tests		

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2025-01-21	D1152500049	Initial
2025-03-28	D1152500051	Revision 1: correction of product version numbers and addition of the former version which will be substituted
2025-04-15	D1152500052	Revision 2: correction regarding product RoboGene HCV RNA Quantification Kit 3.1: self-testing is not applicable