Certificate

mdc medical device certification GmbH
certifies that

Roboscreen GmbH
Hohmannstraße 7
04129 Leipzig
Germany

for the scope

development, manufacture and distribution of molecular biological and immunochemical in-vitro-diagnostics

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

Valid from	2023-04-27
Valid until	2025-03-31
Registration no.	D1152500048
Report no.	P22-01747-253144
Stuttgart	2023-04-27

Head of Certification Body

mdc medical device certification GmbH
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D-70191 Stuttgart, Germany
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Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

Digitally signed by Olaru Victoria
Date: 2025.02.04 12:08:05 EET
Reason: MoldSign Signature
Location: Moldova
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Roboscreen GmbH
Hohmannstraße 7
04129 Leipzig
Germany

Notified Body Confirmation Letter

Registration no.: D1152500049

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 a gradual roll-out of Eudamed, information obligation in case of interruption of supply and 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 the applicable Directive. 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 the applicable Directive.

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) 2023/1860), are shown below:

- 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, 2025-01-21

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 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
RoboGene HBV DNA Quantification Kit 3.0	☒ 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	-	D1152500044 D1152500046 NB# 0483
RoboGene HCV RNA Quantification Kit 3.0	☒ 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	-	D1152500044 D1152500043 NB# 0483
RoboGene HDV RNA Quantification Kit 3.0	☒ 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	-	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 ☐ 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
2025-01-21	D1152500049	Initial

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith grants

Roboscreen GmbH
Hohmannstraße 7
04129 Leipzig
Germany

for the scope

RoboGene HDV RNA Quantification Kit 2.0

the

EC Design Examination Certificate

The examination of the design of the product by mdc has proven
that the design meets the requirements according to

Annex IV – Section 4
of the Council Directive 98/79/EC

of the European Parliament and of the Council of
27 October 1998 on in vitro diagnostic medical devices.

This certificate is only valid in connection with a valid mdc certificate
according to Annex IV – excluding section 4 and 6 for the above mentioned products.

Valid from	2022-05-13
Valid until	2025-05-26
Registration no.	D1152500047
Report no.	P22-00120-238119
Stuttgart	2022-05-13

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten ZLG-BS-247.10.05

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EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

Roboscreen GmbH
Hohmannstraße 7
04129 Leipzig
Germany

for the scope

molecular diagnostic kits for
quantitative determination of Hepatitis Virus B, C and D

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

Annex IV – excluding Section 4 and 6 of the Council Directive 98/79/EC

of the European Parliament and of the Council of
27 October 1998 on in vitro diagnostic medical devices.

The surveillance will be held as specified in Annex IV, Section 5.

Valid from	2022-04-11
Valid until	2025-05-26
Registration no.	D1152500044
Report no.	P22-00120-226744
Stuttgart	2022-04-11

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten ZLG-BS-247.10.05

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