

Declaration of conformity

Name and address of company

Roboscreen GmbH
Hohmannstrasse 7
04129 Leipzig
Germany

We the **Roboscreen GmbH** declare on our own responsibility that the medical device

Name: **RoboGene HDV RNA Quantification Kit 2.0**

Catalogue number: **847-0207400582/ 847-0207400584
847-0207400542/ 847-0207400544**

Description: **Quantitative real time PCR test**

meets all applicable requirements of the Directive 98/79/EC Annex I.

In the context of conformity with the Directive 98/79/EC, the standards referred to in Chapter 12 of the Technical Documentation have been fully or partially applied.

Responsible notified body

Name: **mdc medical device certification GmbH**
Address: **Kriegerstraße 6 in 70191 Stuttgart, Germany**
Identification number: **0483**

Conformity assessment
procedure: **Directive 98/79/EC, Annex IV**

Classified as follows
according to the directive
98/79/EC: **Device of List A, Annex II**

Validity: **26.05.2025**

Place: Leipzig

Date: 13.05.2022

Name und Function: Dr. Ingolf Lachmann, CEO

Legally binding signature:



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