

**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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CEO  
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