

## 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 HCV RNA Quantification Kit 3.0**

*Catalogue number:* **847-0207610032; 847-0207610096; 847-0207610192**

*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: **31.12.2027**

Place: Leipzig

Date: 30.01.2025

Name und Function: Dr. Ingolf Lachmann, CEO

Legally binding signature:



Roboscreen GmbH  
Hohmannstraße 7  
04129 Leipzig • Germany

CEO  
Dr. Ingolf Lachmann

Phone: +49 341 989 734 0  
Fax: +49 341 989 734 199  
[info@roboscreen.com](mailto:info@roboscreen.com)  
[www.roboscreen.com](http://www.roboscreen.com)

Ust-IdNr. DE 813064314  
County Court Leipzig  
HRB 17503  
Leipzig