ROBOSCREEN
DIAGNOSTICS

# *EU Declaration of Conformity*

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| *Name and address of Manufacturer:* | Roboscreen GmbH<br>Hohmannstrasse 7<br>04129 Leipzig,<br>Deutschland |
| *SRN of Manufacturer:* | DE-MF-000024661 |

The **Roboscreen GmbH** declares on own responsibility that the medical device

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| *Name:* | RoboGene HBV DNA Quantification Kit 3.1 |
| *Catalogue number:* | 847-0207720032, 847-0207720096; 847-0207720192 |
| *Description:* | Real-time PCR based quantitative detection of HBV-DNA in human blood plasma and serum |
| *Basic-UDI-DI:* | 4262386730207721CQ |
| *Risk class:* | Class D |

meets all applicable requirements of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices. In the context of conformity with the mentioned regulation the standards referred to in chapter 4.1 of the Technical Documentation have been fully or partially applied.

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| *Applied conformity assessment procedure:* | Annex IX chapter I (Quality Management System), chapter II (Assessment of the Technical Documentation) and chapter III (Administrative Provisions) |
| *Applied CS:* | Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 |
| *Name and reference number of notified body:* | mdc medical device certification GmbH, Stuttgart<br>Reference number 0483 |
| *Certificate issued by the notified body:* | EU Quality Management System Certificate<br>Registration No. D1152500053<br>EU Technical Documentation Assessment Certificate<br>Registration No. D1152500054 |
| Validity (DD.MM.YYYY): | 01.04.2031 |
| Place: | Leipzig |
| Date: | 27.05.2026 |
| Name and Function: | Dr. Ingolf Lachmann, CEO |
| Legally binding signature: | |

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