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Nur zur elektronischen Verbreitung

EU Technical Documentation Assessment Certificate

We hereby certify that the company

Roboscreen GmbH
Hohmannstraße 7
04129 Leipzig
Germany

has submitted a technical documentation in accordance with Annexes II and III of Regulation (EU) 2017/746, which meets the following requirements:

Annex IX – Chapter II (Assessment of the Technical Documentation)

of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 2 pages. Details of the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2026-04-02	Registration No.	D1152500054
Valid until	2031-04-01	Report No.	P25-00872-340985

Stuttgart, 2026-04-02

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-098

Devices:

RoboGene HBV DNA Quantification Kit 3.1
Art.Nr. 847-0207720032, 847-0207720096; 847-0207720192

Intended purpose: RoboGene HBV DNA Quantification Kit 3.1 is a nonautomated in vitro diagnostic test, based on real-time PCR technology, for quantification of Hepatitis B Virus (HBV) DNA (genotypes A-H) in human EDTA-plasma samples. RoboGene HBV DNA Quantification Kit 3.1 is intended for quantification of HBV DNA as an aid in the management of patients with HBV infection undergoing antiviral therapy. All results must be interpreted within the context of all relevant clinical and laboratory findings. RoboGene HBV DNA Quantification Kit 3.1 has not been approved as a screening test for the presence of HBV in blood or blood products. RoboGene HBV DNA Quantification Kit 3.1 is intended for use by professional users trained in molecular biological techniques and in vitro diagnostic procedures.

Risk class: D
Basic UDI-DI: 4262386730207721CQ

Notes:

For the placing on the market of the devices an EU Quality Management System Certificate according to Annex IX, Chapter I of Regulation (EU) 2017/746 on in vitro diagnostic medical devices is also required.