

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**Roboscreen GmbH  
Hohmannstraße 7  
04129 Leipzig  
Germany**

for the scope

**molecular diagnostic kits for  
quantitative determination of Hepatitis Virus B, C and D**

has introduced and applies a

**Quality System**

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system  
meets all requirements according to

**Annex IV – excluding Section 4 and 6  
of the Council Directive 98/79/EC**

of the European Parliament and of the Council of  
27 October 1998 on in vitro diagnostic medical devices.

The surveillance will be held as specified in Annex IV, Section 5.

Valid from	2022-04-11
Valid until	2025-05-26
Registration no.	D1152500044
Report no.	P22-00120-226744
Stuttgart	2022-04-11

  
Head of Certification Body



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-247.10.05