ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 18 01 92378 005

Manufacturer:

Healgen Scientific Limited Liability Company
3818 Fuqua Street
Houston TX 77047
USA

EC-Representative:

Qarad b.v.b.a
Cipalstraat 3
B-2440 GEEL
BELGIUM

Product: **Screening test for Hepatitis C marker**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. See also notes overleaf.

Report No.: SH1898802

Valid from: 2018-04-27
Valid until: 2022-06-28

Date, 2018-04-27

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

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No. V7 18 01 92378 005

Model(s): **HCV Hepatitis C Virus Rapid Test**

Parameters:

Model Name:	Model No.:
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HCV Hepatitis C Virus Rapid Test (Serum / Plasma) (Cassette)	GCHCV-302a
HCV Hepatitis C Virus Rapid Test (Whole Blood /Serum / Plasma) (Cassette)	GCHCV-402a

Facility(ies): **Zhejiang Orient Gene Biotech Co., Ltd. 3787#, East Yangguang Avenue, Dipu Street Anji, 313300 Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA**

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