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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 079456 0005 Rev. 01

Manufacturer: **Hain Lifescience GmbH**
Hardwiesenstr. 1
72147 Nehren
GERMANY

Product Category(ies): **Products for determination of infection markers and of HLA tissue types**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V1 079456 0005 Rev. 01

Report no.: 713251868_SCN

Valid from: 2022-04-27
Valid until: 2025-05-26

Date, 2022-04-27

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Model(s): **Products acc. to Annex II List B (NA Reagents for Detection of Chlamydia and CMV, HLA-Typing Reagents)**

Facility(ies): Hain Lifescience GmbH
Hardwiesenstr. 1, 72147 Nehren, GERMANY

Parameters:

GenoQuick® HLA-B27 VER 2.0 and **FluoroType® HLA-B27 VER 1.0**, assay for the biomolecular detection of the human HLA-B27 gene from whole blood for diagnosis of associated illnesses, especially Bechterew's disease;
FluoroType® CT VER 1.0, assay for the biomolecular detection of Chlamydia trachomatis from swabs, urine and ejaculate samples;
FluoroType® CMV VER 1.0, assay for the quantitative detection of Cytomegalovirus DNA from human EDTA plasma and urine samples;
FluoroType® CMV HT VER 1.0, assay for the automated quantification of Cytomegalovirus DNA from human EDTA plasma and urine samples;
FluoroType® STI VER 1.0, multiplex assay for the detection of sexually transmitted pathogens including Chlamydia trachomatis from urine samples or genital swabs.

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