ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 17 04 95186 005

Manufacturer: **EUROCLONE DIAGNOSTICA S.R.L.**
Via Lombardia, 12
27010 Siziano (PV)
ITALY

Facility(ies): EUROCLONE DIAGNOSTICA S.R.L.
Via Lombardia, 12, 27010 Siziano (PV), ITALY

Product Category(ies): **Products for determination of infection markers**
HLA typing

Model(s): **Kit for molecular biology for determining human infectious diseases (Chlamydia and Cytomegalovirus) and genotyping HLA-B polymorphisms disease by Real-Time PCR**

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. See also notes overleaf.

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Valid from: 2017-06-03
Valid until: 2022-06-02

Date, 2017-05-31

Stefan Preiß

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

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