



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 11 07 40885 014

Manufacturer: **Quidel Corporation**
 10165 McKellar Court
 San Diego, CA 92121
 USA

Facility(ies): Quidel Corporation
 10165 McKellar Court, San Diego, CA 92121, USA

Product Category(ies): **Reagents for determination of Chlamydia Trachomatis**

Model(s): **Quickvue Chlamydia**

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.

Report no.: SM1104542

Valid from: 2011-07-01

Valid until: 2015-11-23



Date, 2011-07-01

Hans-Heiner Junker

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

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