

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1418003-1

Organization: QIAGEN N.V.
Hulsterweg 82
5912 PL Venlo
Netherlands

Scope: Design and development, manufacture, distribution, installation and service of in-vitro diagnostic systems used in the diagnosis, management and detection of cancer, compatibility testing, disease status, genetic testing, immune status, prenatal screening, sexually transmissible agents and transmissible agents.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1101776-10
Effective date: 2022-05-03
Expiry date: 2024-06-14
Issue date: 2022-05-03




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The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o QIAGEN N.V. Hulsterweg 82 5912 PL Venlo Netherlands	Management of the global QM System and administration.
/02	c/o QIAGEN GmbH Qiagen Str. 1 40724 Hilden Germany	Design and development, manufacture, distribution, installation and service.
/03	c/o QIAGEN Business Services Sp. z o.o. ul. Powstańców Śląskich 95 53-332 Wrocław Poland	Design and development of Software, administration service for manufacture distribution, installation and service.

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The scope of certification also covers the following:

No.	Facility	Scope
/04	c/o QIAGEN Manchester Ltd. Citylabs 2.0 200 Hathersage Road Manchester M13 0BH United Kingdom	Design and development.
/05	c/o QIAGEN Ltd. Citylabs 2.0 200 Hathersage Road Manchester M13 0BH United Kingdom	Installation, service and distribution.

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