

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1285228-1

Organization: QIAGEN Manchester Ltd.
Skelton House
Lloyd Street North
Manchester
M15 6SH
United Kingdom

Scope: The design and development of molecular diagnostic reagents and instruments used in the field of human genetic analysis and in the diagnosis, management and detection of sexually transmissible agents, transmissible agents and cancer.

Installation, service and distribution of molecular diagnostic and immunological reagents, instruments and software used in the diagnosis, management and detection of sexually transmissible agents, transmissible agents, human genetic analysis and cancer, including devices for sample preparation.

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.: 3333684-90

Effective date: 2020-11-03

Expiry date: 2023-11-02

Issue date: 2020-11-02





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The scope of certification also covers the following:

No.	Facility	Scope
/01	QIAGEN Manchester Ltd. Skelton House Lloyd Street North Manchester M15 6SH United Kingdom	The design and development of molecular diagnostic reagents and instruments used in the field of human genetic analysis and in the diagnosis, management and detection of sexually transmissible agents, transmissible agents and cancer.
/02	QIAGEN Ltd. Skelton House Lloyd Street North Manchester M15 6SH United Kingdom	Installation, service and distribution of molecular diagnostic and immunological reagents, instruments and software used in the diagnosis, management and detection of sexually transmissible agents, transmissible agents, human genetic analysis and cancer, including devices for sample preparation.

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