

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1614112-1

Organization: KABE-Labortechnik GmbH
Jägerhofstr. 17
51588 Nümbrecht
Germany

Scope: Design and development, production and distribution of in vitro diagnostic devices and consumption materials for sample withdrawal, preparation and storage as well as single-use medical devices

TÜVRheinland

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.: 1092786-40
Effective date: 2021-10-25
Expiry date: 2024-10-15
Issue date: 2021-10-25



Dipl.-Ing. F. Schwingen
TÜV Rheinland LGA Products GmbH
Lillystraße 2 · 90431 Nürnberg · Germany



Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1614112-1

Organization: KABE-Labortechnik GmbH
Jägerhofstr. 17
51588 Nümbrecht
Germany

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o KABE-Labortechnik GmbH Jägerhofstr. 17 51588 Nümbrecht Germany	Design and development, production and distribution of in vitro diagnostic devices and consumption materials for sample withdrawal, preparation and storage as well as single-use medical devices
/02	c/o KABE-Labortechnik GmbH Werner-von-Siemens-Str. 1 51674 Wiehl Germany	Warehouse

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Dipl.-Ing. F. Schwingen
TÜVRheinland LGA Products GmbH
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EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60150763 0001

Report No.: 21234760 013

Manufacturer: KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

Products:

- Cannulas for blood collection
- MBU Capillaries

(see attachment for details)

Replaces certificate, Registration No.: HD 60105393 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-10-07

Date: 2020-10-07

Notified Body


Dr. K. Kluge



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Certificate**

Registration No.: HD 60150763 0001
Report No.: 21234760 013

Manufacturer: KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

Products included:

- Cannulas for blood collection

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:

- MBU Capillaries

Date: 2020-10-07

Notified Body

Dr. K. Kluge
Dr. K. Kluge

