ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

M.S.D.N: 0105835905 - C.T.C.P
CÔNG TY CỔ PHẦN THỤ TINH TRONG ỐNG NGHIỆM VIỆT ĐỨC
THÀNH PHỐ HÀ NỘI

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 18 04 70354 009

Manufacturer:

Labotect Labor-Technik-Göttingen GmbH
Kampweg 12
37124 Rosdorf
GERMANY

Facility(ies):

Labotect Labor-Technik-Göttingen GmbH
Kampweg 12, 37124 Rosdorf, GERMANY

BeLoTec GmbH
Kampweg 12, 37124 Rosdorf, GERMANY

Product Category(ies):

Sterile medical products and medical products for assisted reproduction, consisting of biopsy needles and sets for follicle aspiration, suction pumps, cell and tissue culture systems

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 categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713132064

Valid from: 2018-07-11
Valid until: 2023-07-10

Date, 2018-07-11

Stefan Preiß

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

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TÜV SÜD
Product Service

Certificate

No. Q5 070354 0010 Rev. 00

Holder of Certificate: **Labotect Labor-Technik-Göttingen GmbH**
Kampweg 12
37124 Rosdorf
GERMANY

Facility(ies):
BeLoTec GmbH
Kampweg 12, 37124 Rosdorf, GERMANY

Labotect Labor-Technik-Göttingen GmbH
Kampweg 12, 37124 Rosdorf, GERMANY

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production, sale and service of sterile medical devices (intrauterine catheters, biopsy needles and sets for ultrasonic aspiration, micropipettes) and medical devices for assisted reproduction and for cell and tissue cultures; Installation, maintenance and repair of laboratory equipment and active medical devices in addition to logistics services**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713149250

Valid from: 2019-04-12
Valid until: 2022-04-11

Date, 2019-04-12

Stefan Preiß

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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