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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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)
(Class IM)

No. G1 060982 0011 Rev. 03

Manufacturer: SHANGHAI LINK INSTRUMENTS CO.,LTD.
No.1101 Huyi Road, Shanghai, 201802, China

Product Category(ies): Ophthalmic A Scan, Corneal Topographer, Vision Screener, Optical Biometer, Fundus Camera, Specular Microscope, Rebound Tonometer and Delta Ophthalmic Ultrasound Scan,Synoptophore Auto Refractometer,Auto Lensmeter,Trial frame

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.: BJ19967022

Digitally signed by Bas Dumitru
Date: 2024.03.27 08:57:48 EET
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Valid from: 2020-01-14
Valid until: 2024-05-26

Date, 2020-01-14

Christoph Dicks
Head of Certification/Notified Body

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

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Facility(ies):

SHANGHAI LINK INSTRUMENTS CO.,LTD.
No.1101 Huyi Road, Shanghai, 201802, China

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