

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten ZLG-BS-244.10.08

EC Certificate

Production Quality Assurance System Directive 93/42/EEC on Medical Devices, Annex V (Devices in class I with measuring function)

No. G2M 069181 0007 Rev. 01

Manufacturer:

Lianyungang TianNuo Optical Instrument Co., Ltd

No.3 JinQiao Road, Dapu Industria 222000 Lianyungang, Jiangsu PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International/Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, GERMANY

Sets, Trial Frames.

Product Category(ies):

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for the manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Trial Lenses

Report No.:

Tiant Valid from: Valid until:

2019-03-18

BJ1971707

2019-03-18 2024-03-03

V.

Stefan Preiß



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



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REGISTRATION NO. 04719Q10000896

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of Lianyungang TianNuo Optical Instrument Co., Ltd.

Registered Address: No.3 JinQiao Road, Dapu Industrial park, Lianyungang, Jiangsu, China

Postcode: 222000

Manufacturing Address: No.3 JinQiao Road, Dapu Industrial park, Lianyungang, Jiangsu, China

Has been assessed and conformed to the following standard(s) YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The Design, Development, Production And Service Of Trial Lens Set, Trial Frame

> Date of issue: July 22,2019 Date of expiry: July 21,2022

General Manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (www.cmca.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, In Dian Men Weistenet, Donochang district, Beiling 100011, P.R. China Telephone; 010-62351993