



Sunkingdom Med. Co. Ltd

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

**ChongQing Sunkingdom Medical
Instrument Co.Ltd**

35-2-3, YingTianGuangDianGongGu,
CaiJiaGang Industry Zone, ChongQing, China

MedNet GmbH

Borkstrasse 10, 48163 Münster, Germany

We, the manufacturer, herewith declare that the products

Ophthalmic Slit Lamp

Type: LS-1, LS-2, LS-3, LS-4, LS-5, LS-6, LS-7

UMDNS-Code: **12-281**

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX, Rule 12 of the Directive 93/42/EEC. It bears the mark



Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: ChongQing Sunkingdom Medical Instrument Co.Ltd

Address: 35-2-3, YingTianGuangDianGongGu, CaiJiaGang Industry Zone, ChongQing, China

Place, date

ChongQing 08.11.2015



Legally binding signature, Function

Li Wei

EC Declaration of Conformity
ECD0C150701A

Management System Certificate

Certificate No.: 10000422254-MSC-NA-CHN

Initial Certification Date: 18 May 2021

Valid Until: 18 May 2024

This is to certify that the quality system of:

ChongQing Sunkingdom Medical instrument Co., Ltd.

No.1 XinMao Road (Free Trade Zone), BeiBei District, ChongQing, China.
(Unicode: 915001097874714975)

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016/NS-EN ISO 13485:2016

This certificate is valid for the following scope:

**DESIGN, DEVELOPMENT, MANUFACTURE, DISTRIBUTION, SERVICE AND SALES OF
FUNDUS CAMERA, PERIMETER, OPHTHALMIC SLIT LAMP MICROSCOPE,
OPHTHALMIC ULTRASOUND EXAMINATION INSTRUMENT, VISUAL
ELECTROPHYSIOLOGY, LENSMETER, OCULAR SURFACE ANALYZER AND
APPLANATION TONOMETER.**

Place and date:
Høvik, 18 May 2021

Check Validity



For the issuing office:
DNV Product Assurance AS



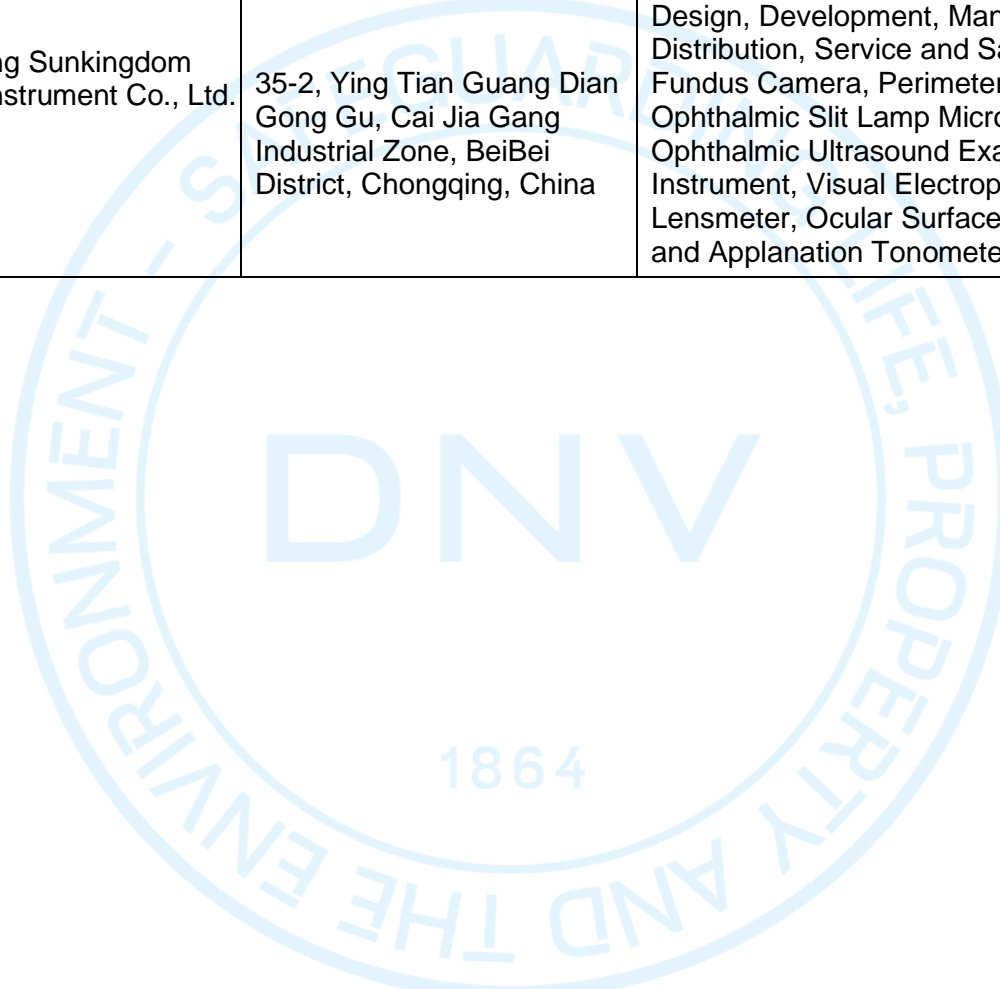
Hazem Tinawi
Technical Reviewer

icate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

Certificate No.: 10000422254-MSC-NA-CHN Rev. 0.0
Place and date: Høvik, 18 May 2021

Site name	Site address	Site specific scope
ChongQing Sunkingdom Medical instrument Co., Ltd.	No.1 XinMao Road (Free Trade Zone), BeiBei District, ChongQing, China	Legal Registered Address
	35-2, Ying Tian Guang Dian Gong Gu, Cai Jia Gang Industrial Zone, BeiBei District, Chongqing, China	Design, Development, Manufacture, Distribution, Service and Sales of Fundus Camera, Perimeter, Ophthalmic Slit Lamp Microscope, Ophthalmic Ultrasound Examination Instrument, Visual Electrophysiology, Lensmeter, Ocular Surface Analyzer and Applanation Tonometer.

End of Certificate



Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

Accredited Body: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-i1-ISO13485-f1,

rev.0