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Date: 2024.03.29 09:43:56 EET
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Location: Moldova

EC Declaration of Conformity

Manufacturer:
Ningbo Ming Sing Optical R&D Co., Ltd.
Address:No.702,North Tiantong Road, Yinzhou district, Ningbo, Zhejiang Province, 315192. P.R.China.

Whose single Authorized Representative:
Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

We, the manufacturer, herewith declare that the products

AUTO REF/KERATOMETER

Model: KR-9000, KR-9200, KR-9, KR-9300
RM-9000, RM-9200, RM-9, RM-9300
KR-9600, VX90, KR-9800, VX95
RM-9600, RM-9800, FA-6500A, FA-6500K

UMDNS-Code:

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

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

CE 1639

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

SGS Belgium NV

SGS House Noorderlaan 87 2030 Antwerp Belgium

Certificate No.: CN19/41105
Issue date: 16.Dec.2021
Expiry date: 12.Nov.2025

following the procedure relating to the EC Declaration of Conformity set out in Annex V 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: Ningbo Ming Sing Optical R&D Co., Ltd.,
Address: No.702,North Tiantong Road, Yinzhou district, Ningbo, Zhejiang Province, 315192. P.R.China.

Place , Ningbo

Date: 20th Dec, 2021

Signature, Function
International trade manager

EC Declaration of Conformity
CE-02- 03 B/0