



Declaration of Conformity

No.: RATF1008/21

Issuer's name: Menicon Co., Ltd.
 Issuer's address: 3-21-19, Aoi, Naka-ku, Nagoya, 460-0006 Japan

Object of the declaration:

Miru 1month Menicon Silicone Hydrogel Contact Lens
Miru 1month Menicon for Astigmatism Silicone Hydrogel Contact Lens
Miru 1month Menicon toric Silicone Hydrogel Contact Lens
Miru 1month Menicon Multifocal Silicone Hydrogel Contact Lens
Miru 1month Menicon multifocal Silicone Hydrogel Contact Lens
and its other trade names (see attached list)

Indication: They are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and/or astigmatism) and/or presbyopia in not-aphakic persons with non-diseased eyes. The lenses are chemically disinfected.

This declaration covers all lots for these products manufactured by the date of expiry.

We declare, under our sole responsibility, that the products identified in this declaration are in conformity with the requirements of the following documents:

| <u>Documents</u> | <u>Title/Content</u> | <u>Date of issue</u> |
|-----------------------------|--|----------------------|
| MDD | Council Directive 93/42/EEC of 14 June 1993 concerning medical devices | 14 June, 1993 |
| EN ISO 13485 2016 + AC 2016 | Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016) | March 2016 |
| EN ISO 14534 2015 | Ophthalmic optics – Contact lenses and contact lens care products – Fundamental requirements (ISO14534:2011) | January 2015 |

Additional information:

Annex II was chosen as the "Conformity Assessment Route",
 Medical device classification: IIa
 EC Certificate number: D1005900021
 Date of expiry: 23 August, 2023

Conformity assessment body information:

Name: mdc medical device certification GmbH
 Address: Kriegerstrasse 6, 70191 Stuttgart, Germany
 ID number: 0483

03 Sep 2020
 (Date of issue)

3-21-19, Aoi, Naka-ku, Nagoya, 460-0006 JAPAN
 (Place)

General Manager of Regulatory Affairs
 (Title)

Tetsuji Kawai
 (Tetsuji Kawai)