Menicon

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:

Documents	Title/Content	Date of issue
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)