



## 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)