

Appendix 1

Declaration of Conformity



Declaration of Conformity

No.: RATF1008/20e

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

24 Dec 2019
 (Date of issue)

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

General Manager of Regulatory Affairs
 (Title)

Tetsuji Kawai
 (Tetsuji Kawai)



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1month Menicon Private Label:

- love spheric
- love toric
- love multifocal
- oculsoft® Monthly FRESH SPHERIC
- oculsoft® Monthly FRESH TORIC
- oculsoft® Monthly FRESH MULTIFOCAL
- PRIMAsoft® OXY contact lenses
- PRIMAsoft® OXY contact lenses TORIC
- procis PREMIUM SILIKON HYDROGEL-LENSES
- procis PREMIUM TORIC SILIKON HYDROGEL-LENSES
- procis PREMIUM MULTIFOCAL SILIKON HYDROGEL-LENSES
- Get Argus® Eyes Diamond plus
- Get Argus® Eyes Diamond toric
- Get Argus® Eyes Diamond multifocal
- 30 DAYS OF HAPPINESS sferisch
- 30 DAYS OF HAPPINESS torisch
- 30 DAYS OF HAPPINESS multifocaal
- Optiview Nash maandlenzen sferisch
- Optiview Nash maandlenzen torisch
- Optiview Nash maandlenzen multifocaal
- COMFORT LENS PREMIUM sphärische Silikon-Hydrogel Monatslinse
- COMFORT LENS PREMIUM torische Silikon-Hydrogel Monatslinse
- COMFORT LENS PREMIUM multifokale Silikon-Hydrogel Monatslinse
- SENSITIVELENS MED Sphärische Silikon-Hydrogel Monatslinse
- SENSITIVELENS MED Torische Silikon-Hydrogel Monatslinse
- SENSITIVELENS MED Multifokale Silikon-Hydrogel Monatslinse
- BRILLANT LENS + SPHERIC
- BRILLANT LENS + TORIC
- BRILLANT LENS + MULTI
- VISEA SENSITIVE SPHERIC
- VISEA SENSITIVE TORIC
- VISEA SENSITIVE MULTIFOCAL
- kloss optimum lens
- kloss optimum lens toric
- kloss optimum lens multifocal
- prima-lens silicon elite plus
- prima-lens silicon elite toric plus
- prima-lens silicon elite multifocal plus
- eye² MY.AIR Monats-Kontaktlinsen Sphärisch
- eye² MY.AIR Monats-Kontaktlinsen Torisch
- eye² MY.AIR Monats-Kontaktlinsen Multifocal

- KRASS AQUA MONTH
- KRASS AQUA TORIC
- KRASS AQUA MULTI
- Premium Lens live sphärisch
- Premium Lens live torisch
- Premium Lens live multifokal
- oogwereld Sferische
- oogwereld Torische
- oogwereld Multifocale
- PRO EYES KONTAKTLINSEN YOU LOOK PERFECT KOMFORT+ sphärisch
- PRO EYES KONTAKTLINSEN YOU LOOK PERFECT KOMFORT+ torisch
- PRO EYES KONTAKTLINSEN YOU LOOK PERFECT KOMFORT+ multifocal
- Aqua Rubin Six Spheric Monthly
- Aqua Rubin Six Toric Monthly
- Aqua Rubin Six Multifocal Monthly
- Medivent Evolution Miu
- Medivent Evolution Miu Toric
- Medivent Evolution Miu Multifocal
- EXCELLENS EXTRA
- EXCELLENS EXTRA TORIC
- EXCELLENS EXTRA MULTIFOCAL
- fino
- fino toric
- fino multifocal
- evO₂lution monthly lenses
- Biocomfort Elite
- Biocomfort Elite toric
- Biocomfort Elite multifocali
- INTERLENS HIOX SPHERIC
- INTERLENS HIOX TORIC
- INTERLENS HIOX MULTI
- OPTIME 1month
- ONE MONTH SPHERIC LENSES
- ONE MONTH TORIC LENSES
- ONE MONTH MULTIFOCAL LENSES
- LENTI A CONTATTO MENSILI SFERICHE
- LENTI A CONTATTO MENSILI TORICHE
- LENTI A CONTATTO MENSILI MULTIFOCALI
- OPTIMEDICS® EXCELLENCE
- OPTIMEDICS® EXCELLENCE TORIC
- AUGENOPTIK VOß SPHERIC
- AUGENOPTIK VOß TORIC
- AUGENOPTIK VOß MULTIFOCAL
- wesee Sferiche
- wesee Astigmatiche
- wesee Multirelax
- augen auf! Monatskontaktlinsen sphärische
- augen auf! Monatskontaktlinsen torische
- augen auf! Monatskontaktlinsen multifokale
- eye+con sensitive sphärisch
- eye+con sensitive torisch
- eye+con sensitive multifokal
- Optica Diviniti Oxy Pro 161 Spheric
- Optica Diviniti Oxy Pro 161 Toric
- Optica Diviniti Oxy Pro 161 Multifocal

- **Tinzi Optik sphärische Monatskontaktlinsen**
- **Tinzi Optik torische Monatskontaktlinsen**
- **Tinzi Optik multifokale Monatskontaktlinsen**
- **simply!®love sph**
- **simply!®love tor**
- **simply!®love mul**
- **Curschmann Kontaktlinsen sphärisch**
- **Curschmann Kontaktlinsen torisch**
- **Curschmann Kontaktlinsen multifokal**
- **EyeLove DeLuxe**
- **EyeLove DeLuxe Toric**
- **newvision MONTHLY SPHERIC**
- **newvision MONTHLY TORIC**
- **newvision MONTHLY MULTIFOCAL**
- **CLEAR LENS PLUS SPHERIC**
- **CLEAR LENS PLUS TORIC**
- **CLEAR LENS PLUS MULTIFOCAL**
- **OCULIST Elite**
- **OCULIST Elite Toric**
- **OCULIST Elite Multifocal**
- **EYE.FRESH AIR 2 SPHÄRISCH**
- **EYE.FRESH AIR 2 TORISCH**
- **EYE.FRESH AIR 2 MULTIFOKAL**
- **Haru Monthly Lenses**
- **Haru Monthly Toric**
- **Haru Monthly Multifocal**
- **Natsu Monthly Lenses**
- **Natsu Monthly Toric**
- **Natsu Monthly Multifocal**
- **Aki Monthly Lenses**
- **Aki Monthly Toric**
- **Aki Monthly Multifocal**
- **MEDIFREE BEST+++**
- **MEDIFREE BEST+++ toric**
- **MEDIFREE BEST+++ multifokal**
- **OTTICA BALZAROTTI 1month SFERICHE**
- **OTTICA BALZAROTTI 1month TORICHE**
- **OTTICA BALZAROTTI 1month MULTIFOCALI**
- **PRIMAsoft® OXY contact lenses Multifocal**
- **SYDROSPHER**
- **SYDROTORIC**
- **SYDROMULTI**
- **COOL^{me} sphärisch**
- **COOL^{me} torisch**
- **COOL^{me} multifokal**
- **one month spheric**
- **one month toric**
- **one month multifocal**
- **Linsentraum LT mi sphärisch**
- **Linsentraum LT mi torisch**
- **Linsentraum LT mi multifokal**
- **monopticien.com 1month Menicon**
- **monopticien.com 1month Menicon for Astigmatism**
- **monopticien.com 1month Menicon Multifocal**
- **MIRICAL Sphärische Silikon-Hydrogel-Monatskontaktlinse**

- **MIRICAL Torische Silikon-Hydrogel-Monatskontaktlinse**
- **MIRICAL Multifokale Silikon-Hydrogel-Monatskontaktlinse**
- **aktiv**
- **aktiv torisch**
- **aktiv zoom**
- **AQUACON AIR SPHERIC**
- **AQUACON AIR TORIC**
- **AQUACON AIR MULTIFOCAL**
- **Verkerk Maand 6 sferische maandlenzen**
- **Verkerk Maand 6 torische maandlenzen**
- **Verkerk Maand 6 multifocale maandlenzen**
- **OPTIME 1month Toric**
- **OPTIME 1month Multifocal**
- **DOCTOR LENS MONTHLY SPHERIC**
- **DOCTOR LENS MONTHLY TORIC**
- **DOCTOR LENS MONTHLY MULTI**
- **SINSIGHT 3 Lenti mensili Sferiche**
- **SINSIGHT 3 Lenti mensili Toriche**
- **SINSIGHT 3 Lenti mensili Multifocali**
- **FIRST OPTIKER WEICHE MONATSLINSEN SPHÄRISCHE**
- **FIRST OPTIKER WEICHE MONATSLINSEN TORISCHE**
- **FIRST OPTIKER WEICHE MONATSLINSEN GLEITSICHT**
- **ONDA spheric**
- **ONDA toric**
- **ONDA multifocal**
- **irridi ONE-MONTH CONTACT LENSES (3 LENSES)**
- **irridi ONE-MONTH CONTACT LENSES (6 LENSES)**
- **fresh SPHÄRISCHE MONATSLINSEN**
- **fresh TORISCHE MONATSLINSEN**
- **fresh MULTIFOKALE MONATSLINSEN**
- **Die Linse sphärisch Silikon-Hydrogel-Monatslinsen**
- **Die Linse torisch Silikon-Hydrogel-Monatslinsen**
- **Die Linse multifokal Silikon-Hydrogel-Monatslinsen**
- **MARIA Meine Monatslinse sphärisch**
- **MARIA Meine Monatslinse torisch**
- **MARIA Meine Monatslinse multifokal**
- **evO2lution monthly lenses for ASTIGMATISM**
- **evO2lution monthly lenses MULTIFOCAL**
- **MONTHLY VIEW Spheric**
- **MONTHLY VIEW Toric**
- **MONTHLY VIEW Multifocal**
- **VEDERBENE keep in contact 3 monthly spheric**
- **VEDERBENE keep in contact 3 monthly toric**
- **VEDERBENE keep in contact 3 monthly multifocal**
- **irridi ONE-MONTH CONTACT LENSES MULTIFOCAL**
- **irridi ONE-MONTH CONTACT LENSES FOR ASTIGMATISM**
- **OPTILAND Supreme**
- **OPTILAND Supreme Toric**
- **OPTILAND Supreme Multifocal**
- **Prime 1 month**
- **Prime 1 month toric**
- **Prime 1 month multifocal**