



ST.SHINE OPTICAL CO., LTD.

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精華光學股份有限公司
新北市汐止區221大同路一段276號5樓

EC Declaration of Conformity

Manufacturer: St. Shine Optical Co., Ltd.
4, 5F., No. 276-2, Sec. 1, Ta Tung Rd., Hsi Chih Dist.,
New Taipei City 221, Taiwan

EU Representative: Emergo Europe
Prinsessegracht 20, 2514 AP The Hague,
The Netherlands

Product: Disposable Contact lenses, Si-Hy Disposable Contact
Lenses
Described in List of CE-marked Device

Classification: IIa, rule 5 according to Annex IX of the MDD

Conformity assessment route:
93/42/EEC (MDD), Annex II, Section 3 (Annex II excluding
(4))

We hereby declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards applied: Harmonized standards
EN 1041:2008, EN 62366:2008, EN ISO 10993-1:2009, EN ISO 10993-5:2009,
EN ISO 10993-11:2018, EN ISO 11607-1:2020, EN ISO 11607-2:2020,
EN ISO 11737-1:2006, EN ISO 11737-2:2020, EN ISO 13485:2016,
EN ISO 14971:2019, EN ISO 15223-1:2016, EN ISO 17665-1:2006
ISO standards
ISO 10993-10:2010, ISO 11981:2017, ISO 11987:2012, ISO 18369-1:2017,
ISO 18369-2:2017, ISO 18369-3:2017, ISO 18369-4:2017, ISO 14644-1 :2015,
ISO 14644-2 :2015, ISO 14644-3 :2019

Notified Body: SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium

(EC) Certificate(s): TW19/20058

Products covered: Lot numbers and date of first CE-marking are as shown in
List of CE-marked Device

Place, Date of Issue: Taipei, 2022/6/27

Signature:  (Johnson Chou)

Managing Director
St. Shine Optical Co., Ltd.