

EC Certificate Full Quality Assurance System: Certificate TW19/20058

The management system of

ST. Shine Optical Co., Ltd.

4,5F., No.276-2, Sec. 1, Ta Tung Rd., Hsi Chih Dist.,
New Taipei City 221, Taiwan

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2019 until 29 March 2024
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 02 October 2013
and first certified by SGS Belgium NV since 16 December 2019

This is a multi-site certification.

Additional site details are listed on subsequent pages

Certification is based on reports numbered TW/TPE K605875

Authorised by

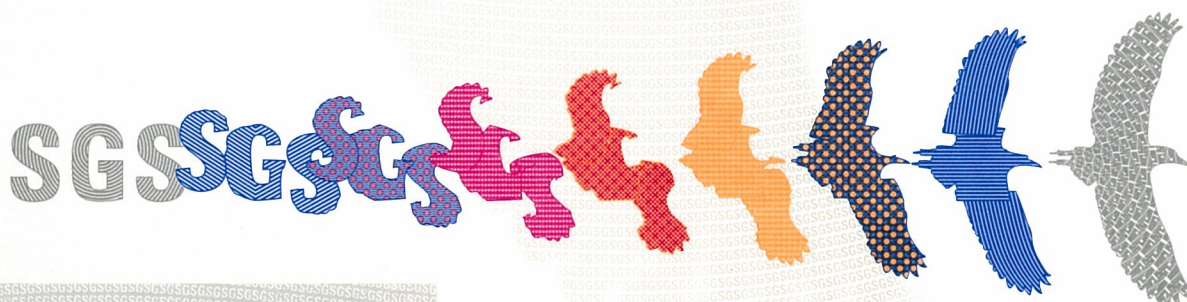


SGS Belgium NV, Notified Body 1639

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ST. Shine Optical Co., Ltd.

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4).

Issue 1

Detailed scope

**Sterile soft contact lenses;
Sterile moulded soft contact lenses.**

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

4F, 7F, No. 306-3, Sec. 1 Ta Tung Rd., Hsi Chih Dist.,
New Taipei City 221, Taiwan

No. 147, Kang Ning St., Hsi Chih Dist.,
New Taipei City 221, Taiwan

3, 4F., No. 308-6, Sec. 1, Ta Tung Rd., Hsi Chih Dist.,
New Taipei City 221, Taiwan

4F-1, 5F-1, No. 239, Sec. 1, Ta Tung Rd., Hsi Chih Dist.,
New Taipei City 221, Taiwan

No. 46, Dunan St., Qidu Dist.,
Keelung City, Taiwan

5F, 6F, No.93, Sec. 1, Xintai 5th Rd., Hsi Chih Dist.,
New Taipei City 221, Taiwan

ST. Shine Optical Co., Ltd.

Certificate Sites
4, 5F., No. 276-2, Sec. 1, Ta Tung Rd., Hsi Chih Dist., New Taipei City 221, Taiwan

Scope:

Certificate Scope (EN) Sterile soft contact lenses; Sterile moulded soft contact lenses.

This corrigendum is only valid together with accompanying 93/42/EEC certificate issue 1

<u>Correction Date</u>	<u>Correction</u>
Change approved by SGS on 03 September 2021	Change of Scope Sterile moulded soft contact lenses.

Authorised by



Global Medical Devices Certification Manager

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LPMD5105 – Corrigendum to Certificate

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SGS Belgium NV

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