

EC Certificate Full Quality Assurance System: Certificate GB98/14374

The management system of

The Fred Hollows Intraocular Lens Laboratory

Tilganga Eye Centre, Gaushala, Bagmati Bridge,
Pashupatinath, Kathmandu, Nepal

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

Sterile One-piece rigid PMMA intraocular lenses, Sterile foldable acrylic intraocular lenses and Sterile PMMA capsular tension rings.

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.

This certificate is valid from 26 June 2016 until 29 January 2021
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 29 January 2019

Issue 11. Certified since 30 August 1998

Certification is based on reports numbered GB/PI 09107

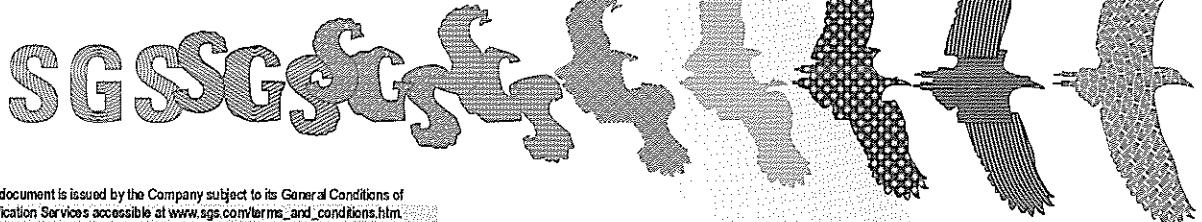
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Certificate GB98/12525

The management system of

The Fred Hollows Intraocular Lens Laboratory

Tilganga Eye Centre, Gaushala, Bagmati Bridge,
Pashupatinath, Kathmandu, Nepal



has been assessed and certified as meeting the requirements of

ISO 13485:2003 EN ISO 13485:2012

For the following activities

Design and manufacture of Sterile one-piece rigid PMMA intraocular lenses, Sterile foldable acrylic intraocular lenses and Sterile PMMA capsular tension rings.

This certificate is valid from 26 June 2016 until 29 January 2019 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 29 January 2019

Issue 13. Certified since 08 April 1998

Authorised by

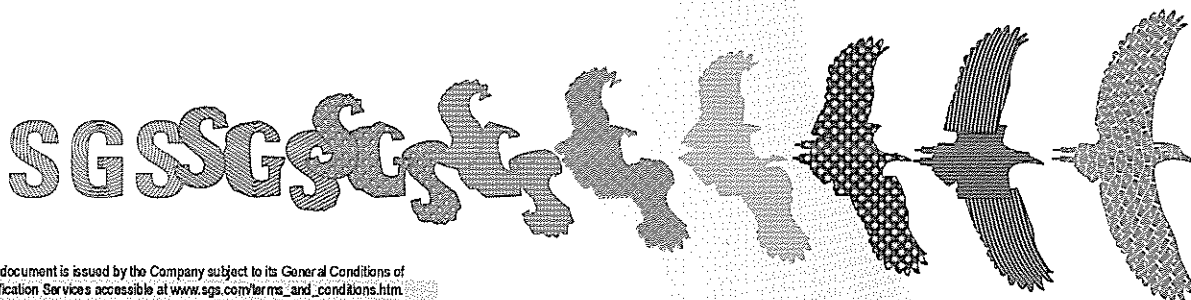


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Certificate GB04/61005

The management system of

The Fred Hollows Intraocular Lens Laboratory

Tilganga Eye Centre, Gaushala, Bagmati Bridge,
Pashupatinath, Kathmandu, Nepal

has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

**Design and manufacture of Sterile one-piece rigid PMMA
intraocular lenses, Sterile foldable acrylic intraocular
lenses and Sterile PMMA capsular tension rings.**

Further clarifications regarding the scope of this certificate and the applicability of
ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 29 January 2016 until 15 September 2018
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 15 September 2018
Issue 7. Certified since 29 January 2004



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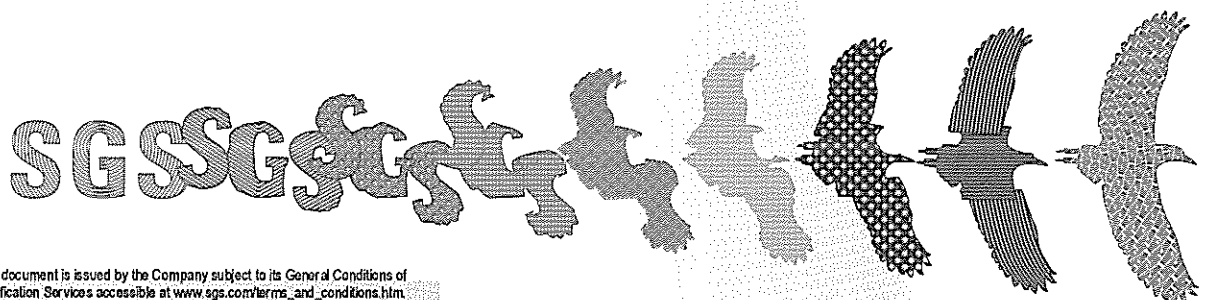
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