



America

CERTIFICATE

No. QS6 097247 0011 Rev. 00

Certificate Holder:

Supervision Optimax Sdn Bhd
Lot 38, Putra Industrial Park
Bukit Rahman Putra
40160 Sungai Buloh, Selangor
MALAYSIA

Certification Mark:



Scope of Certificate:

**Design and Development, Manufacturing and Distribution
of Soft Contact Lenses**

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

**Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA.
See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website <https://www.tuev-sued.de/product-testing/certificates>

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No:

53-440-9121

Effective Date:

2019-04-10

Expiry Date:

2022-04-09

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Date of Issue: 2019-04-16

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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Regulatory Requirements: Audit/Certification Criteria

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations SOR/98-282, Part 1

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Facility(ies):

Supervision Optimax Sdn Bhd
 Lot 38, Putra Industrial Park, Bukit Rahman Putra, 40160
 Sungai Buloh, Selangor, MALAYSIA

Facility Scopes:

Design and Development, Manufacturing and Distribution of
 Soft Contact Lenses
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US-Letter / 07.17