

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

CorneaGen
101 North Chestnut Street, Suite 303
Winston-Salem
North Carolina
27101
USA

Holds Certificate Number:

FM 555653

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The manufacture, final inspection and distribution of ophthalmic surgical instruments.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2010-03-12

Latest Revision Date: 2024-11-19

Effective Date: 2025-02-16

Expiry Date: 2028-02-15

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