

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Tecfen Medical
6100 Hollister Avenue
Building 3, unit 3A/3B
Santa Barbara
California
93117
USA

Holds Certificate Number:

MD 654311

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

Manufacturing, procurement, sale and distribution of surgical instruments used in ophthalmic surgery and other customer applications

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2016-07-29

Latest Revision Date: 2024-08-06

Effective Date: 2024-08-10

Expiry Date: 2027-08-09



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