



TREPHINE PRODUCTS

**TECFEN MEDICAL OFFERS A COMPREHENSIVE
SELECTION OF CORNEAL TREPHINE BLADES AND TISSUE PUNCHES**

6100 Hollister Avenue
Building 3, Unit 3A/3B
Santa Barbara, CA 93117

(T) 805.967.1153
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tecfen@tecfen.com
www.tecfenmedical.com



Long Trephines (For Donor or Recipient)



PRODUCT NO.	DESCRIPTION	PRODUCT NO.	DESCRIPTION	PRODUCT NO.	DESCRIPTION
QTR330250	2.50mm Diameter	QTR330725	7.25mm Diameter	QTR331150	11.50mm Diameter
QTR330300	3.00mm Diameter	QTR330750	7.50mm Diameter	QTR331200	12.00mm Diameter
QTR330350	3.50mm Diameter	QTR330775	7.75mm Diameter	QTR331250	12.50mm Diameter
QTR330400	4.00mm Diameter	QTR330800	8.00mm Diameter	QTR331300	13.00mm Diameter
QTR330450	4.50mm Diameter	QTR330825	8.25mm Diameter	QTR331350	13.50mm Diameter
QTR330500	5.00mm Diameter	QTR330850	8.50mm Diameter	QTR331400	14.00mm Diameter
QTR330550	5.50mm Diameter	QTR330875	8.75mm Diameter	QTR331450	14.50mm Diameter
QTR330600	6.00mm Diameter	QTR330900	9.00mm Diameter	QTR331500	15.00mm Diameter
QTR330625	6.25mm Diameter	QTR330950	9.50mm Diameter	QTR331550	15.50mm Diameter
QTR330650	6.50mm Diameter	QTR331000	10.00mm Diameter	QTR331600	16.00mm Diameter
QTR330675	6.75mm Diameter	QTR331050	10.50mm Diameter	QTR331650	16.50mm Diameter
QTR330700	7.00mm Diameter	QTR331100	11.00mm Diameter	QTR331700	17.00mm Diameter
				QTR331800	18.00mm Diameter

Non-Vacuum Trephine Punches (For Donor)



Vacuum Trephine Punches (For Donor)



Radial Vacuum Trephines (For Recipient)



PRODUCT NO.	DESCRIPTION
QTR340600	6.00mm Diameter
QTR340625	6.25mm Diameter
QTR340650	6.50mm Diameter
QTR340675	6.75mm Diameter
QTR340700	7.00mm Diameter
QTR340725	7.25mm Diameter
QTR340750	7.50mm Diameter
QTR340775	7.75mm Diameter
QTR340800	8.00mm Diameter
QTR340825	8.25mm Diameter
QTR340850	8.50mm Diameter
QTR340875	8.75mm Diameter
QTR340900	9.00mm Diameter
QTR340925	9.25mm Diameter
QTR340950	9.50mm Diameter

PRODUCT NO.	DESCRIPTION
QTR360600	6.00mm Diameter
QTR360625	6.25mm Diameter
QTR360650	6.50mm Diameter
QTR360675	6.75mm Diameter
QTR360700	7.00mm Diameter
QTR360725	7.25mm Diameter
QTR360750	7.50mm Diameter
QTR360775	7.75mm Diameter
QTR360800	8.00mm Diameter
QTR360825	8.25mm Diameter
QTR360850	8.50mm Diameter
QTR360875	8.75mm Diameter
QTR360900	9.00mm Diameter
QTR360925	9.25mm Diameter
QTR360950	9.50mm Diameter

PRODUCT NO.	DESCRIPTION
QTR370600	6.00mm Diameter
QTR370650	6.50mm Diameter
QTR370700	7.00mm Diameter
QTR370725	7.25mm Diameter
QTR370750	7.50mm Diameter
QTR370775	7.75mm Diameter
QTR370800	8.00mm Diameter
QTR370825	8.25mm Diameter
QTR370850	8.50mm Diameter
QTR370875	8.75mm Diameter
QTR370900	9.00mm Diameter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 602872****Issued To:**

Tecfen Medical
5385 Hollister Avenue
Santa Barbara
California
93111
USA

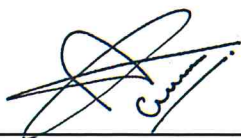
In respect of:

The manufacture of sterile single use disposable ophthalmic surgical knives and sterile single use disposable corneal trephines for use as ophthalmic cutting instruments.

Those aspects of Annex V related to securing and maintaining sterility in the manufacture of sterile PVA and Cellulose Sponge Products.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Albert Roossien, Regulatory Lead

First Issued: **2013-12-17**

Date: **2019-03-06**

Expiry Date: **2023-08-02**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Production Quality Assurance

Supplementary Information to CE 602872

Issued To:

Tecfen Medical
5385 Hollister Avenue
Santa Barbara
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93111
USA

Number	Device Name	Intended purpose per IFU
Class IIa		
MD0105	Ophthalmic surgical knives	N/A
MD0105	Corneal trephines	N/A
Class Is		
MDS7006	Ophthalmic Sponge disposable	N/A

First Issued: **2013-12-17**

Date: **2019-03-06**

Expiry Date: **2023-08-02**

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This certificate was issued electronically and is bound by the conditions of the contract.

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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-07-29

Latest Revision Date: 2022-02-04

Effective Date: 2021-08-10

Expiry Date: 2024-08-09

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

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