



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.

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Supplementary Information to CE 602872

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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

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