



Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlín, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 13 0517 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the products – medical devices of Class IIa

Ophthalmic Blades

(For detailed specification refer to the annex; pages 1-1)

manufactured by company

Microtrack Surgicals

**A - 38, Adarsh - II, Industrial Estate, B/h. Ashish Cinema, Odhav,
Ahmedabad - 382 415, Gujarat, India**

are manufactured under conditions fulfilling the quality system requirements of Annex V, Section 3.2., of the Directive 93/42/EEC.

The Notified Body No. 1023 has performed an audit of the above products manufacturing quality system. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex V, Sections 3.3, and 4, of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601866/2013, which is enclosed to this Certificate.

Condition of this Certificate use and related information:

1. *It applies only to the quality system maintained in the manufacture of the above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 3rd June 2018 at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each medical device, of the above referenced models, the CE marking followed by the number of the Notified Body according to this example:*

CE 1023

Issued in Zlín, on 4th June 2013




RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



Annex to EC CERTIFICATE

No. 13 0517 QS/NB

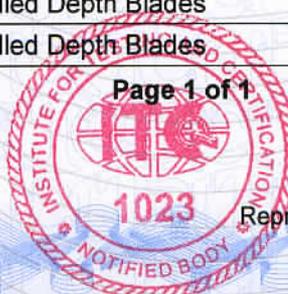
Issued for the company:

Microtrack Surgicals

**A - 38, Adarsh - II, Industrial Estate, B/h. Ashish Cinema, Odhav,
Ahmedabad - 382 415, Gujarat, India**

List of the medical devices covered by the Certificate:

| Catalog No. | Product Description | ANGLES |
|-------------|--|------------------------|
| M921501 | LanceTip 15 Degree | STERIGHT/45DEGREE ANG. |
| M923001 | LanceTip 30 Degree | STERIGHT/45DEGREE ANG. |
| M924501 | LanceTip 45 Degree | STERIGHT/45DEGREE ANG. |
| M940002 | Crescent BevelUp 20G | ANGLED 45DEGREE |
| M943003 | Crescent Bevel Down 20G | ANGLED 45DEGREE |
| M940004 | Crescent Bevel Up 19G | ANGLED 45DEGREE |
| M901861 | 1.8mm Slit Keratome Blades | ANGLED 45DEGREE |
| M902261 | 2.2mm Slit Keratome Bldes | ANGLED 45DEGREE |
| M902561 | 2.5mm Slit Keratome Blades | ANGLED 45DEGREE |
| M902661 | 2.65mm Slit Keratome Blades | ANGLED 45DEGREE |
| M902861 | 2.8mm Slit Keratome Blades | ANGLED 45DEGREE |
| M902961 | 3.0mm Slit Keratome Blades | ANGLED 45DEGREE |
| M903261 | 3.2mm Slit Keratome Blades | ANGLED 45DEGREE |
| M903561 | 3.5mm Slit Keratome Blades | ANGLED 45DEGREE |
| M902868 | 2.8mm Slit Keratome Blades Clear Cornea | ANGLED 45DEGREE |
| M903268 | 3.2mm Slit Keratome Blades Clear Cornea | ANGLED 45DEGREE |
| M902668 | 2.65mm Slit Keratome Blades Clear Cornea | ANGLED 45DEGREE |
| M905161 | 5.1mm Extension Keratome Blades | ANGLED 45DEGREE |
| M905261 | 5.2mm Extension Keratome Blades | ANGLED 45DEGREE |
| M905561 | 5.5mm Extension Keratome Blades | ANGLED 45DEGREE |
| M906061 | 6.0mm Extension Keratome Blades | ANGLED 45DEGREE |
| M965556 | 19G MVR Blades Streight/Angled | ST./ ANGLED 45 DEGREE |
| M965569 | 20G MVR Blades Streight/Angled | ST./ ANGLED 45 DEGREE |
| M965573 | 24G MVR Blades Streight/Angled | ST./ ANGLED 45 DEGREE |
| 300 micron | 300 micron Controlled Depth Blades | ST. |
| 500 micron | 500 Micron Controlled Depth Blades | ST. |
| 600micron | 600 Micron Controlled Depth Blades | ST. |



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