

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60140657 0001

**Report No.:** 21261790 013

**Manufacturer:** Technolas Perfect Vision GmbH  
Messerschmittstr. 1+3  
80992 München  
Deutschland

**Products:** see attachment for products included

Replaces Certificate, Registration No.: 60117551 0001

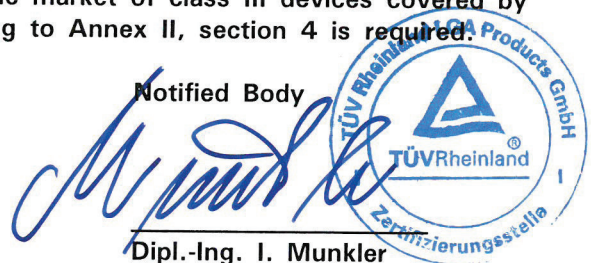
**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2019-07-09

**Date:** 2019-07-09

Notified Body



Dipl.-Ing. I. Munkler

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60140657 0001  
**Report No.:** 21261790 016

**Manufacturer:** Technolas Perfect Vision GmbH  
Messerschmittstr. 1 + 3  
80992 München  
Deutschland

**Products included:**

- Ophthalmic Excimer Laser "TECHNOLAS TENEO 317"
- Calculation Software "ZYOPTIX Treatment Calculator"
- Femtosecond Laser "VICTUS Femtosecond Laser Platform"
- "Patient Interface Kits" for Femtosecond Laser
- Disposable Blades "ACCUGLIDE Disposable Blades"
- Disposable Blades "ZYOPTIX XP Disposable Blades"
- Diagnostic Software "SCORE Analyzer"
- Diagnostic Device "ACE Advanced Corneal Explorer"

For the following medical devices (class I, sterile) the scope covers only the aspects of the manufacture concerned with securing and maintaining sterile conditions:

- "Microkeratome Disposable Tubing" for Zyoptix XP  
Microkeratome and Hansatome

**Date:** 2020-05-06

**Notified Body**

**Roland Gruber**

