

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

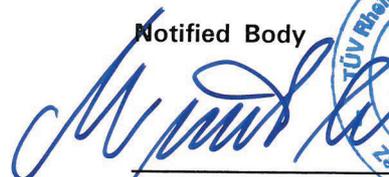
Expiry Date: 2024-05-26

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 TENE0 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

