EC Certificate

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

TÜVRheinland®

Registration No.: HD 60129566 0001

Report No.: 31881530 001

Manufacturer:

Medical Instrument
Development Laboratories, Inc.
557 McCormick Street
San Leandro CA 94577
USA

Products:

Vitreous Cutters, Vitrectomy Units, Cannula Insertion Systems, Tubing Sets, Infusion Sleeves

(see attachment for additional site included)

Replaces Approval, Registration No.: HD 60088829 0001

Expiry Date: 2023-05-27

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: 2018-06-11

Date: 2018-06-11

Notified Body

X. Ren

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60129566 0001
Report No.: 31881530 001

Manufacturer:
Medical Instrument
Development Laboratories, Inc.
557 McCormick Street
San Leandro CA 94577
USA

Additional site:

Medical Instrument Development Laboratories, Inc.
626 Whitney Street
San Leandro, CA 94577 USA

Vitrectomy Units

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

X. Ren

Date: 2018-06-11