EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60129973 0001

Report No.: 12022657 009

Manufacturer:
Inami & Co., Ltd.
3-24-2 Hongo, Bunkyo-ku
Tokyo 113-0033
Japan

Products:
Aspects of manufacture concerned with the conformity of Applanation Tonometer, Light Weight Trial Frame and Synoptiscope with the metrological requirements

(see attachment for site included)

Replaces Approval, Registration No.: DD 60101417 0001

Expiry Date: 2023-09-26

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2018-09-27

Date: 2018-06-01

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Notified Body

M.Sc. M. Aihara

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.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60129973 0001
Report No.: 12022657 009

Manufacturer:
Inami & Co., Ltd.
3-24-2 Hongo, Bunkyo-ku
Tokyo 113-0033
Japan

Site included:

Inami & Co., Ltd., Bijyogi Research Institute
14-12~13, Bijyogi 3-chome, Toda City, Saitama Prefecture,
335-0031, Japan

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Date: 2018-06-01

M.Sc. M. Aihara