

No. 24-2 Hongo 3 Chome, Bunkyo-ku, Tokyo 113-0033, JAPAN Tel: +81 3 3814 5916 Fax: +81 3 5684 2126 corpinfo@inami.co.jp
www.inami.co.jp/english
www.facebook.com/inami.japan

Tokyo, April 14, 2017

To whom it may concern:

CERTIFICATE

We, Inami & Co., Ltd., hereby certify that we have received the following certifications from TUV Rheinland. We are attaching these certifications as evidence.

• DIN EN ISO 9001:2008, JIS Q9001:2008

· ISO 13485:2003, JIS Q 13485:2005

 EC Certificate Directive 93/42/EEC Annex V Production Quality Assurance Medical Devices Registration No. : DD 601014170001 Report No. : 12022657 002



Inami & Co., Ltd.

N ee Taka Inami

CEO





Standard: Certification Registr. No. DIN EN ISO 9001:2008, JIS Q 9001:2008 09 100 89060

TÜV Rheinland Cert GmbH certifies:

Certification Holder:

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

including the locations according to annex

Scope:

Validity:

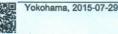
Design, Development, Manufacturing, Sales and Servicing of Ophthalmic Devices Manufacturing and Sales of Ophthalmic Surgical Instruments

An audit was performed, Report No. 89060. Proof has been furnished that the requirements are fulfilled according to DIN EN ISO 9001:2008, JIS Q 9001:2008. The due date for future audits is 06-30 (mm-dd).

This of Eirst

This certificate is valid from 2015-08-01 until 2018-07-31. First certification: 2000 www.tuv.com ID: 0910589060





Y. Sumino TVV Rheinland Cert GmbH Am Grauen Stein 51105 Köln



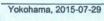
Annex to Certificate

Standard: Certification Registr. No.

DIN EN ISO 9001:2008, JIS Q 9001:2008 09 100 89060

Location:	Inami & Co., Ltd. Head Office: 3-24-2 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan
Scope:	Sales and Servicing of Ophthalmic Devices Manufacturing and Sales of Ophthalmic Surgical Instruments
Certification Registr. No.	09 100 89060/01
Location:	Plant: Bijyogi Research Institute
	3-14-12~13, Bijyogi, Toda City, Saitama Prefecture 335- 0031, Japan
Scope:	Design, Development, Manufacturing and Servicing of Ophthalmic Devices
Certification Registr. No.	09 100 89060/02





TÜV Rheinland Cert GmbH Am Grauen Stein 51105 Köln



CERTIFICATE

Standard: Certification Registr. No. ISO13485:2003, JIS Q 13485:2005 81 105 89060

3-24-2 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan

TÜV Rheinland Japan Ltd. Certifies:

including the locations according to annex

Inami & Co., Ltd.

Certification Holder:

Scope:

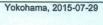
Validity:

Design, Development, Manufacturing, Sales and Servicing of Ophthalmic Devices Manufacturing and Sales of Ophthalmic Surgical Instruments

An audit was performed, Report No. 89060. Proof has been furnished that the requirements are fulfilled according to ISO13485:2003, JIS Q 13485:2005. The due date for future audits is 06-30 (mm-dd).

This certificate is valid from 2015-08-01 until 2018-07-31. First certification: 2009 www.tuv.com ID: 0910589060





Japan Ltd

3-19-5 Shin-Yokohama, Yokohama 222-0033, Japan





Annex to Certificate

Standard: Certification Registr. No. ISO13485:2003, JIS Q 13485:2005 81 105 89060

Location:

Scope:

Certification Registr. No.

Location:

Scope:

Certification Registr. No.

Inami & Co., Ltd. Head Office: 3-24-2 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan Sales and Servicing of Ophthalmic Devices Manufacturing and Sales of Ophthalmic Surgical Instruments 81 105 89060/01

Plant: Bijyogi Research Institute 3-14-12~13, Bijyogi, Toda City, Saitama Prefecture 335-0031, Japan Design, Development, Manufacturing and Servicing of Ophthalmic Devices 81 105 89060/02



Yokohama, 2015-07-29

Rheinland Japan Ltd. 3-19-5 Shin-Yokohama, Yokohama 222-0033, Japan

MS JAB CM046





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

Registration No.: DD 60101417 0001

Report No.: 12022657 002

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 60089490 0001

Expiry Date:

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:

2015-12-17

2018-09-26

Date:

2015-12-17

020 d 04.08 O TUV, TUEV and TUV are registared trademarks. Utilisation and application requires prior approva



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.



Doc. 1/1, Rev. 0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate Registration No.: Report No.:

DD 60101417 0001 12022657 002

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



(90.

Date: 2015-12-17

0 0 0 4 0 8

TUV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval

平成 2 9 年登簿第 207

証

認



嘱託人 井浪 喬之 は、本公証人の面前において別紙編綴の書面に署名した。

よって、これを認証する。

平成29年 4 月 14 日、本公証人役場において

公 証 人 Notary

Masaki Sasaki

総公証 Nº135256 号

証

上記署名は、東京法務局所属公証人の署名に相違ないものであり、かつ、その押印は、 真実のものであることを証明する。

平成29年 4 月 14 日

東京法務局長

佐藤主

CERTIFICATE

This is to certify that the signature affixed above has been provided by Notary, duly authorized by the Tokyo Legal Affairs Bureau and that the Official Seal appearing on the same is genuine.

Date

Chikara SATO

Director of the Tokyo Legal Affairs Bureau

For legalization by the foreign consul in Japan, this is to certify that the Seal affixed hereto is genuine.

APR, 14, 2017

Date APR, 14, 2017

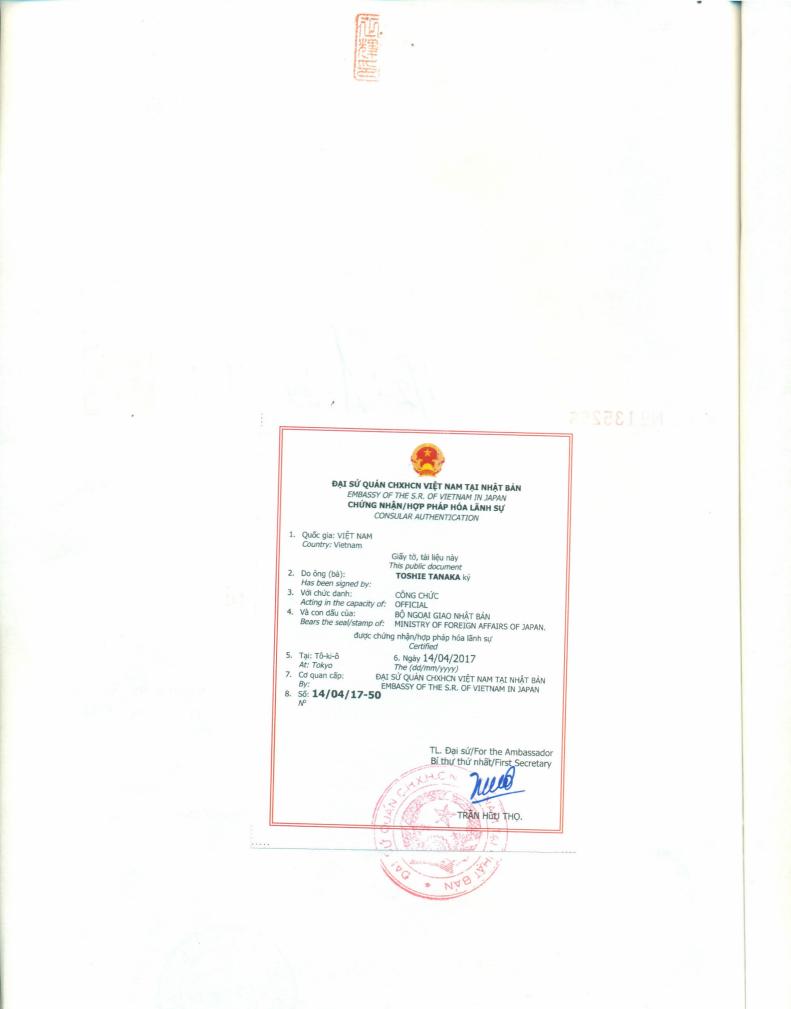
T. TANAKA

Tokyo,

Toshie TANAKA

Official Ministry of Foreign Affairs (Consular Service Division)





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Registered No. 207 of 2017

NOTARIAL CERTIFICATE

This is to certify that Takayuki Inami signed the attached document in my presence on this 14th day of April, 2017.

NOTARY

Masaki Sasaki

Notary, Bunkyo Notary's Office

Tokyo Legal Affairs Bureau,

1-16-21 Kasuga, Bunkyo-ku, Tokyo