



Eye & Health Care

NIDEK CO., LTD.

34-14 Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan
TEL: +81-533-67-8895 FAX: +81-533-68-1320
URL: <http://www.nidek.com>
email: info@nidek.co.jp

21 March, 2017

Ministry of Health

Department of Medical Equipment and Construction

DECLARATION

We NIDEK Co.,Ltd., having its address at 34-14 Maehama, Hiroishi, Gamagori, Aichi, Japan, hereby certify that we hold a following certificate issued by the TUV Product Service GmbH standards.

CERTIFICATE: No. Q1N 16 11 23653 179
Applied Standard(s): EN ISO 13485:2012 + AC:2012
Medical devices – Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009) -
DIN EN ISO 13485:2012

In witness whereof, we attach hereto the above certificate.

Sincerely yours,

Atsushi Tanaka

Corporate Officer and Senior Manager

International Sales Department

International Division

NIDEK CO., LTD.



Product Service

CERTIFICATE

No. Q1N 16 11 23653 179

Holder of Certificate: NIDEK CO., LTD.



34-14 Maehama, Hiroishi-cho, Gamagori
Aichi
443-0038 JAPAN

Facility(ies):

NIDEK CO., LTD., Hiroishi Plant
34-14 Maehama, Hiroishi-cho, Gamagori,
Aichi, 443-0038 JAPAN

NIDEK CO., LTD., Hamacho Plant
67-4 Hama-cho, Gamagori, Aichi, 443-0036
JAPAN



Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Ophthalmic Surgical Lasers, Ophthalmic Ultrasound Equipment, Ophthalmic Diagnostic and Surgical Equipment, Optometric Equipment, Ophthalmic Data Processing Software, Intraocular Lenses

Applied Standard(s):

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: JAQ235026669

Valid from: 2017-04-01

Valid until: 2020-03-31

Date, 2017-03-08

Stefan Preiß



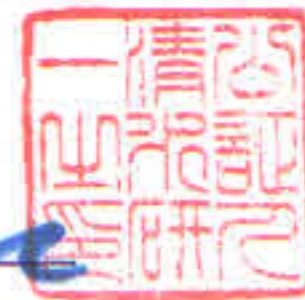
Registered No : 219 2017

Certificate of acknowledgment of Notary

On this 22nd day of March, 2017, before me, Kenichi Shimizu a notary in and for the Tokyo Legal Affairs Bureau, personally appeared Lee Kyungtae, with satisfactory evidence of his identification and of his being an agent of Atsushi Tanaka, Corporate Officer and Senior Manager International Sales Department, International Division of NIDEK CO.,LTD., and in accordance with the Japanese Notary Act, stated that the principal, said Atsushi Tanaka, had acknowledged affixing his signature to the attached document.

In witness whereof, I set my hand and seal







平成29年登簿第 219 号

認 証

株式会社ニデックの国際営業部部長田中敦 (Atsushi Tanaka) の代理人李庚泰は、本職に対し、上記田中敦が添付書面の署名を自認している旨陳述した。

よって、これを認証する。

平成29年 3月22日、本公証人役場において
東京都千代田区鍛冶町1丁目9番4号
東京法務局所属

公 証 人
Notary

清水研一

Kenichi Shimizu



総公証 No 100804 号

証 明

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 3月22日

東京法務局長

佐藤主税



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 Mar.22.2017

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.

Date Mar.22.2017

T. TANAKA

Toshie TANAKA

Tokyo, _____

Official
Ministry of Foreign Affairs
(Consular Service Division)





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Tokyo, _____

Official
Ministry of Foreign Affairs
(Consular Service Division)





ĐẠI SỨ QUÁN CHXHCN VIỆT NAM TẠI NHẬT BẢN
EMBASSY OF THE S.R. OF VIETNAM IN JAPAN
CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia: VIỆT NAM
Country: Vietnam

Giấy tờ, tài liệu này
This public document

2. Do ông (bà):
Has been signed by:

TOSHIE TANAKA ký

3. Với chức danh:
Acting in the capacity of:

CÔNG CHỨC
OFFICIAL

4. Và con dấu của:
Bears the seal/stamp of:

BỘ NGOẠI GIAO NHẬT BẢN
MINISTRY OF FOREIGN AFFAIRS OF JAPAN.

được chứng nhận/hợp pháp hóa lãnh sự
Certified

5. Tại: Tô-ki-ô
At: Tokyo

6. Ngày **22/03/2017**
The (dd/mm/yyyy)

7. Cơ quan cấp:
By:

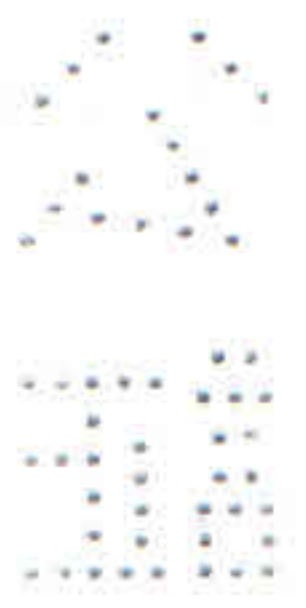
ĐẠI SỨ QUÁN CHXHCN VIỆT NAM TẠI NHẬT BẢN
EMBASSY OF THE S.R. OF VIETNAM IN JAPAN

8. Số: **22/03/17-27**
Nº

TL. Đại sứ/For the Ambassador
Bí thư thứ nhất/First Secretary



№ 100804



T. TANAKA
TOSHIE TANAKA