

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**CANON INC.**  
**MEDICAL EQUIPMENT GROUP**  
**9-1, Imaikami-cho, Nakahara-ku**  
**Kawasaki, Kanagawa 211-8501**  
**Japan**

has established and applies a quality management system for medical devices  
for the following scope:

**See attachments for scope of certification**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012**  
**EN ISO 13485:2012/AC:2012**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2016-09-01  
Certificate Registration No.: SX 60113492 0001  
An audit was performed. Report No.: 12031297 001  
This Certificate is valid until: 2019-02-28

Certification Body



Date 2016-09-01



  
M.Sc. M. Aihara

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/3, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60113492 0001  
**Report No.:** 12031297 001

**Organization:** **CANON INC.**  
**MEDICAL EQUIPMENT GROUP**  
9-1, Imaikami-cho, Nakahara-ku  
Kawasaki, Kanagawa 211-8501  
Japan

**Scope:**

Products included:

- Digital Radiography Devices
- Auto Ref-Keratometers
- Tonometers/Pachymeters
- Optical Coherence Tomography Systems
- Ophthalmic Software for Optical Coherence Tomography Systems and Retinal Cameras

**Certification Body**



**Date:** 2016-09-01

*M. Aihara*  
**M.Sc. M. Aihara**



Doc. 2/3, Rev. 0

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60113492 0001  
**Report No.:** 12031297 001

**Organization:**

**CANON INC.  
MEDICAL EQUIPMENT GROUP  
9-1, Imaikami-cho, Nakahara-ku  
Kawasaki, Kanagawa 211-8501  
Japan**

**Scope:**

Site included:

CANON INC., MEDICAL EQUIPMENT GROUP  
9-1, Imaikami-cho, Nakahara-ku, Kawasaki, Kanagawa  
211-8501, Japan

Scope:

Design/Development, Distribution and Service  
of Digital Radiography Devices,  
Optical Coherence Tomography Systems, Tonometers/Pachymeters  
and Ophthalmic Software for Optical Coherence Tomography  
Systems and Retinal Cameras

**Certification Body**



**Date: 2016-09-01**

*M. Aihara*  
**M.Sc. M. Aihara**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 3/3, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60113492 0001  
**Report No.:** 12031297 001

**Organization:** **CANON INC.**  
**MEDICAL EQUIPMENT GROUP**  
**9-1, Imaikami-cho, Nakahara-ku**  
**Kawasaki, Kanagawa 211-8501**  
**Japan**

**Scope:**

Sites included:

CANON COMPONENTS, INC.  
3461-1 Oaza-Shichihongi, Kamisato-machi, Kodama-gun,  
Saitama, 369-0393, Japan

Scope:

Manufacture and Service of Digital Radiography Devices,  
Optical Coherence Tomography Systems,  
Tonometers/Pachymeters, Ophthalmic Software for  
Optical Coherence Tomography Systems  
and Retinal Cameras, Auto Ref-Keratometers

CANON INC. Utsunomiya Plant  
19-1 Kiyohara-kogyo-danchi, Utsunomiya, Tochigi  
321- 3293, Japan

Scope:

Manufacture and Service of Optical Coherence  
Tomography Systems

**Certification Body**



**Date:** 2016-09-01

*M. Aihara*  
**M.Sc. M. Aihara**



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

1. Quốc gia: VIỆT NAM  
Country: Viet Nam  
Giấy tờ, tài liệu này  
This public document
  2. Do ông (bà): **TOSHIE TANAKA** ký  
Has been signed by
  3. Với chức danh: **CÔNG CHỨC**  
Acting in the capacity of **OFFICIAL**
  4. Và con dấu của: **BỘ NGOẠI GIAO NHẬT BẢN**  
Bears the seal/stamp of: **MINISTRY OF FOREIGN AFFAIRS OF JAPAN**
- được chứng nhận/hợp pháp hóa lãnh sự  
Certified
5. Tại: Tô-ki-ô  
At: Tokyo
  6. Ngày: 22/01/2018  
The (dd/mm/yyyy)
  7. Cơ quan cấp: ĐÀI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI NHẬT BẢN  
By: **EMBASSY OF THE S.R. VIET NAM IN JAPAN**
  8. Số: **22/01/18-022/HPHLS**  
N°

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

