



Ministry of Health, Welfare and Sport  
CI&G  
P.O. Box 16114  
2500 BC The Hague  
THE NETHERLANDS



## STATEMENT

The undersigned herewith declares that according to the Decree on Medical Devices, which is based on the European Directive 93/42/EEC concerning medical devices,

Canon Medical Systems Europe B.V.  
Zilverstraat 1  
2718 RP Zoetermeer  
THE NETHERLANDS

acts as authorised representative of the manufacturer.

The manufacturer:

Canon Medical Systems Corporation  
1385, Shimoishigami, Otawara-Shi  
Tochigi 324-8550  
JAPAN

is authorised to manufacture and/or supply the medical device/devices mentioned below:

### See product list

This device/these devices may be placed on the Dutch market and on the markets of the other Member States of the European Union, and be exported to non-EU Member States. This free sale certificate may only be used for export outside the European Union.

The present statement is drawn up at the request of the interested party in order to be submitted to the Health Authorities of **VIETNAM**.

This statement is valid until May 26, 2024.

The Hague, October 30, 2020



On behalf of the Minister for Medical Care and Sport  
Farmatec | CI&G

Dr. M.J. van de Velde

Mr. M.J. van de Velde  
Head of Department

Our reference: 20205112  
Certificate number: 29505



CT SCANNER Alexion MODEL TSX-032A  
CT SCANNER Alexion MODEL TSX-033A  
CT SCANNER Alexion MODEL TSX-034A  
CT SCANNER Aquilion MODEL TSX-201A  
CT SCANNER Aquilion Lightning MODEL TSX-035A  
CT SCANNER Aquilion Lightning MODEL TSX-036A  
CT SCANNER Aquilion ONE MODEL TSX-305A  
CT SCANNER Aquilion Prime SP MODEL TSX-303B  
CT SCANNER Aquilion ONE MODEL TSX-306A  
CT SCANNER Aquilion Start MODEL TSX-037A  
CT SCANNER Aquilion Precision MODEL TSX-304A  
Vantage Elan MODEL MRT-2020  
Vantage Galan 3T MODEL MRT-3020  
Vantage Orian MRT-1550

**DIAGNOSTIC ULTRASOUND SYSTEM Aplio a450 MODEL CUS-AA450**

**DIAGNOSTIC ULTRASOUND SYSTEM Aplio a550 MODEL CUS-AA550**

**DIAGNOSTIC ULTRASOUND SYSTEM Aplio a MODEL CUS-AA000**

DIAGNOSTIC ULTRASOUND SYSTEM Aplio i600 MODEL TUS-AI600  
DIAGNOSTIC ULTRASOUND SYSTEM APLIO i700 MODEL TUS-AI700  
DIAGNOSTIC ULTRASOUND SYSTEM APLIO i800 MODEL TUS-AI800  
DIAGNOSTIC ULTRASOUND SYSTEM APLIO i900 MODEL TUS-AI900  
DIAGNOSTIC ULTRASOUND SYSTEM XARIO 100 MODEL TUS-X100S  
DIAGNOSTIC ULTRASOUND SYSTEM Xario100G MODEL CUS-X100G  
DIAGNOSTIC ULTRASOUND SYSTEM Xario200G MODEL CUS-X200G  
INTERVENTIONAL ANGIOGRAPHY SYSTEM Alphenix MODEL INFX-8000F  
INTERVENTIONAL ANGIOGRAPHY SYSTEM Alphenix MODEL INFX-8000C  
INTERVENTIONAL ANGIOGRAPHY SYSTEM Alphenix MODEL INFX-8000V  
INTERVENTIONAL ANGIOGRAPHY SYSTEM Alphenix MODEL INFX-8000H  
MULTIPURPOSE REMOTE CONTROL R/F SYSTEM Ultimax-i DREX-UI80  
RADIOGRAPHIC SYSTEM RADREX MRAD-A80S  
RADIOGRAPHIC SYSTEM RADREX MRAD-A50S




Dr. M.J. van de Velde



The attached document is verified and issued as true "Statement" (consisting of two (2) pages, each page bearing my civil law notary's signature and seal) regarding **CANON MEDICAL SYSTEMS EUROPE B.V.**, issued on behalf of the Ministry of Health, Welfare and Sport, by me, mr. Ronald Jozef Krol, civil law notary at Zoetermeer (the Netherlands), on this 6<sup>th</sup> day of November 2020.



  
R.J. Kro  
civil law notary

### Legalisation

Seen for legalisation of the signature of

**mr. R.J. Krol**  
acting in the capacity of notary at Zoetermeer

Date: 06-11-2020  
No.: 2020-8660



By me, President of the District Court of Justice Den Haag,

mr. M.A. van de Laarschot



Ministerie van Buitenlandse Zaken

Gezien voor legalisatie van de handtekening  
*The undersigned legalises the signature*

van/of **M.A. van de Laarschot**

De minister van Buitenlandse Zaken, voor deze,  
*For the minister of Foreign Affairs,*



09 nov 2020 - F.S. Moeniralam

NL 04 90890





**CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ**  
**CONSULAR AUTHENTICATION**

1. Quốc gia/ *Country*: **VIỆT NAM**  
*Giấy tờ, tài liệu này / This public document*
2. do ông (bà) **F.S. Moeniralam** ký  
*has been signed by*
3. với chức danh **Viên chức BNG Hà Lan**  
*acting in the capacity of*
4. và con dấu của: **Bộ Ngoại giao Hà Lan**  
*bears the seal/stamp of*  
được chứng nhận/hợp pháp hóa lãnh sự / *certified*
5. tại/àt: **The Hague** 6. Ngày/the: **9 / 11 / 2020**
7. Cơ quan cấp/ by: **Đại sứ quán Việt Nam tại Hà Lan**
8. Số/ No: **197** / 2020

**TL. Đại sứ**  
**Tham tán**



**Nguyễn Hoàng Hải**