CERTIFICATE

Number: 2217500

The management system of:

Philips Medical Systems Nederland B.V.

Veenpluis 4-6
5684 PC Best
The Netherlands

Manufacturer DUNS 413819707

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia:	-	Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil:	-	RDC ANVISA N. 162013, 232012, 672009
Canada:	-	Medical Devices Regulations - Part 1- SOR 98282
Japan:	-	MHLW Ministerial Ordinance 169, Article 4 to Article 68
	-	PMD Act
United States:	-	21 CFR 803
	-	21 CFR 806
	-	21 CFR 807 - Subparts A to D
	-	21 CFR 820

Scope:
Design and development, manufacture, distribution, installation and service of Diagnostic X-Ray systems and associated software and hardware for the area of interventional and surgical procedures.
Design and development, manufacture, distribution, installation and service of Hemodynamic monitoring software for the area of interventional and surgical procedures.

Certificate expiry date: 1 February 2021
Certificate effective date: 4 September 2018
Certified since: 7 March 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ir. H. van der Woord
Certification Manager

DEKRA Certification B.V. is recognised under the Medical Devices Single Audit Program.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

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