EC CERTIFICATE

Number: 2079177CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Philips Medical Systems Nederland B.V.

Veenpluis 4-6
5684 PC Best
The Netherlands

For the product category(ies)

Diagnostic X-Ray systems and associated software and hardware for the area of interventional and surgical procedures

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2079177CN, initially dated 25 January 2005
Addendum, initially dated 1 February 2005

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 July 2020
Issued for the first time: 1 February 2005
Reissued: 10 November 2016

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2079177CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Diagnostic X-Ray systems and associated software and hardware for the area of interventional and surgical procedures

Issued to:

Philips Medical Systems Nederland B.V.
Veenpluis 4-6
5684 PC Best
The Netherlands

This certificate covers the following product(s):

This certificate covers the activities of the Business Innovation Unit Interventional X-Ray-Best of the certification holder.

Allura Xper Series (class IIb):
Allura Xper FD10
Allura Xper FD20
Allura Xper FD10/10
Allura Xper FD20/10
Allura Xper FD20/15
Allura Xper FD20/20

Allura Xper OR Table Series (class IIb):
Allura Xper FD10 OR Table
Allura Xper FD20 OR Table
Allura Xper FD10/10 OR Table
Allura Xper FD20/10 OR Table
Allura Xper FD20/15 OR Table
Allura Xper FD20/20 OR Table

Allura Centron (class IIb)
BV Pulsera (class IIb)
BV Endura (class IIb)
Veradius (class IIb)
Veradius Unity (class IIb)

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2079177CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Diagnostic X-Ray systems and associated software and hardware for the area of interventional and surgical procedures

Issued to:

Philips Medical Systems Nederland B.V.
Veenpluis 4-6
5684 PC Best
The Netherlands

Interventional tools (class IIa):
Interventional Workspot
Allura 3D-RA
3D Roadmap
MR-CT Roadmap
XperCT
XperCT Dual
XperGuide
Stentboost
2D Perfusion
EchoNavigator
EmboGuide
HeartNavigator
EP navigator
VesselNavigator
AneurysmFlow
2D Quantitative Analysis
StentBoost Live
Dynamic Coronary Roadmap
3D-RA

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2079177CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Diagnostic X-Ray systems and associated software and hardware for the area of interventional and surgical procedures

Issued to:

Philips Medical Systems Nederland B.V.
Veenpluis 4-6
5684 PC Best
The Netherlands

Azurion Series (Class IIb):
Azurion 7 M12
Azurion 7 M20
Azurion 3 M12
Azurion 3 M15

All certified devices are manufactured in the facility:
Philips Medical Systems Nederland B.V., Veenpluis 4-6, 5684 PC Best, The Netherlands

The BV Endura and BV Pulsera devices are also manufactured in the subcontractor facility:
Philips India Limited., Plot no. B-79, MIDC, Phase-II, Chakan, Taluka-khed, Village – Savardari, District: Pune, Maharashtra 410 501, India

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2079177CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Diagnostic X-Ray systems and associated software and hardware for the area of interventional and surgical procedures

Issued to:

Philips Medical Systems Nederland B.V.
Veenpluis 4-6
5684 PC Best
The Netherlands

The following Class IIb products, which are no longer in production, are still subject to refurbishment:

- Integris Allura 9C (last produced: 2007)
- Integris Allura 9F (last produced: 2007)
- Integris Allura 9 Biplane (last produced: 2005)
- Integris Allura 12 & 15 Monoplane(last produced: 2008)
- Integris Allura 12 & 15 Biplane (last produced: 2006)
- OmniDiagnost Eleva (last produced: 2010)
- UroDiagnost Eleva (last produced: 2007)
- Allura CV20 (last produced: 2013)
- MultiDiagnost Eleva (class IIb) (last produced: 2015)
- BV Libra (class IIb) (last produced: 2015)

Initial date: 1 February 2005
Revision date: 12 June 2017

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396