CERTIFICATE

Number: 78318CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Issued to:

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

For the product category:

Magnetic Resonance Systems for diagnostic imaging and interventional 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 78318CN, initially dated 17 December 1997
Addendum, initially dated 1 January 2001

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex II for class IIa products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II, section 4 is mandatory. The necessary information 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 2017
Issued for the first time: 1 January 1995
Reissued: 28 December 2013

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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ADDENDUM

Belonging to certificate: 78318CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Magnetic Resonance Systems for diagnostic imaging and interventional procedures

Issued to:

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The Netherlands

This certificate covers the following product(s):

INTERA family (class IIa):
- INTERA 1.5T

ACHIEVA family (class IIa):
- ACHIEVA 1.5T
- ACHIEVA 3.0T
- ACHIEVA XR

INGENIA family (class IIa):
- INGENIA 1.5T
- INGENIA 3.0T

High Field Open (class IIa):
- PANORAMA HFO

Work Stations (class IIa):
- Extended MR Workspace (EWS)

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

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Certification Manager

ADDENDUM

Belonging to certificate: 78318CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Magnetic Resonance Systems for diagnostic imaging and interventional procedures

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The following Class IIa products, which are no longer in production, are still subject to refurbishment:
Gyroscan ACS-NT
Gyroscan Intera 1.5T
Intera Achieva 1.5T
Panorama 1.0T

Initial date: 1 January 2001
Revision date: 12 September 2012

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager