SIEMENS

EC DECLARATION OF CONFORMITY

Manufacturer	Siemens Healthcare GmbH Henkestr. 127 91052 Erlangen Germany
Facility	Siemens Healthcare GmbH Advanced Therapies Siemensstr. 1 91301 Forchheim Germany
Type of device	Stationary angiographic x-ray system, digital
Medical device	Artis zee, Artis zeego
Product identification	see next page
GMDN Code and Term:	37623, Stationary angiographic x-ray system, digital
Classification	Class IIb (according to Annex IX to Council Directive 93/42/EEC)

We declare that the above medical device is in conformity with the following Directive(s):

Council Directive 93/42/EEC
The conformity of the full quality assurance system according to Annex II without Chapter II.4 is certified by:

TÜV SÜD Product Service GmbH
Ridlerstrasse 65
80339 Muenchen
Germany

The identification number of the notified body for implementation of the procedure set out in Annex II to the above Directive is 0123.

Directive 2011/65/EU of the European Parliament and of the Council

Relevant Harmonized Standard: EN 50581:2012

This declaration of conformity is issued under the sole responsibility of Siemens Healthcare GmbH.

This declaration supersedes any declaration issued previously for the same product.

Place and date	Forchheim, December 11th, 2015	
Name	Dr. Heiner Kolem (Head of Business Area Advanced Therapies)	Siegfried Schneider (Head of Quality & Technology of Business Area Advanced Therapies)
Siemens Healthcare GmbH Signature	ppa Kolem	i.V. Siegfried Schneider

For conditions of guarantee and liability please refer to our General Conditions of Sale.

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Product identification

Artis zee floor	Part No. 10094135
Artis zee ceiling	Part No. 10094137
Artis zee multi-purpose	Part No. 10094139
Artis zee biplane	Part No. 10094141
Artis zeego	Part No. 10280959

DECLARATION OF CONFORMITY