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	Mobile x-ray c-arm unit for fluoroscopy
Medical device	Cios Alpha
Product identification	10308191
GMDN Code and Term	37649 Portable general-purpose fluoroscopic 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, October 17, 2016	
Name	Dr. Heinrich Kolem (Head of Business Area Advanced Therapies)	Siegfried Schneider (Head of Quality & Technology of Business Area Advanced Therapies)
Siemens Healthcare GmbH		
Signature		

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

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