

EC DECLARATION OF CONFORMITY

Manufacturer Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany

Facility Siemens Healthcare GmbH
SYNGO (SY)
Siemensstr. 1, 91301 Forchheim, Germany

Type of device PACS

Medical device syngo.plaza

Product identification VB30 (Model: 11293724)

Serial Number 500001

GMDN Code and Term 41670, Radiology picture archiving and communication system application software

Classification Class IIa (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.

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.


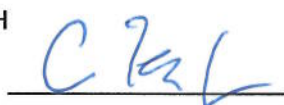
Place and date Forchheim, 2019-11-06

Name Christian Zapf
(Head of Business Unit)

Thomas Frank
(Quality Management Representative)

Siemens Healthcare GmbH

Signature



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

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