

EC DECLARATION OF CONFORMITY

Manufacturer Siemens Shenzhen Magnetic Resonance Ltd.
Siemens MRI Center, Gaoxin C. Ave., 2nd, Hi-Tech
Industrial Park, 518057, Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

Facility Siemens Shenzhen Magnetic Resonance Ltd.
Siemens MRI Center, Gaoxin C. Ave., 2nd, Hi-Tech
Industrial Park, 518057, Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

Authorized Representative Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany

Device Type X-Ray Angiography, Fluoroscopic, Radiographic-system

Medical device Artis one

Product identification 10848600

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 Directives:

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 Munich
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 Shenzhen Magnetic Resonance Ltd.

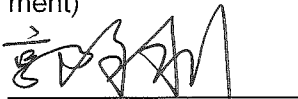
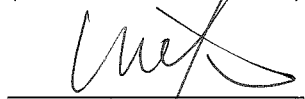
This declaration supersedes any declaration issued previously for the same product.

Place and date Shenzhen, 03, 04, 2020

Name Ye Wei
(Head of Business Unit)

Guo Yong Li
(Head of Quality Management)

Signature



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

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