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.