EC DECLARATION OF CONFORMITY

Manufacturer Facility	Siemens Shanghai Medical Equipment Ltd.(SSME) Siemens Shanghai Medical Equipment Ltd.XP Facility 278 Zhou Zhu Road Shanghai 201318 China
Authorized Representative	Siemens Healthcare GmbH Henkestr. 127 91052 Erlangen GERMANY
Type of device Medical device	X-Ray Radiography System MULTIX Impact
Product identification	11020788
GMDN Code and Term	37645, X-ray system, diagnostic, general-purpose, stationary, 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

This declaration of conformity is issued under the sole responsibility of SSME.

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

Place and date	Shanghai, Jan 31, 2019	
Name	Mr. Du Jian (Head of SSME XP)	Mr. Liu Cong Zhi (Director of SSME XP QA)
Signature		

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

Digitally signed by Belan Irina
Date: 2022.07.08 15:39:59 EEST
Reason: MoldSign Signature
Location: Moldova

EU DECLARATION OF CONFORMITY