EC DECLARATION OF CONFORMITY

Manufacturer	Siemens Healthcare GmbH Henkestr. 127 91052 Erlangen Germany
Facility	Siemens Healthcare GmbH X-Ray Products (XP) Siemensstr. 1, 91031 Forchheim Germany
Type of device	X-ray system for whole body diagnosis
Medical device	MOBILETT Elara Max
Product identification	11107444
GMDN Code and Term:	37647, Mobile basic diagnostic 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, 15.10.18	
Name	Carsten Bertram (Head of Business Unit)	Jürgen Buckow (Head of Quality Management)
Siemens Healthcare GmbH		
Signature	i.V.	i.V.

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