

EU DECLARATION OF CONFORMITY

Manufacturer

Name: Siemens Healthcare GmbH
Address: Henkestr. 127
91052 Erlangen
Germany

Single Registration

Number (SRN): DE-MF-000006122

Facility

Name: Siemens Healthcare GmbH
X-Ray Products (XP)
Address: Siemensstr. 1,
91301 Forchheim,
Germany

Product Identification

Product/Trade Name: MOBILETT Impact
Model: 11647500
System Version: VC10
Basic UDI-DI: 0405686901982WK
UDI-DI: 04056869297309

Nomenclature Code

GMDN Code: 37647
GMDN Term: Mobile basic diagnostic x-ray system, digital
EMDN Code: Z11039016
EMDN Term: Mobile Radiographic Units

Classification

Risk Class: Class IIb (according to rule 10 Annex VIII Medical Device Regulation (EU) 2017/745)

Intended Purpose Statement under Regulation (EU) 2017/745:

Mobile X-ray system intended for various procedures that visualizes a variety of anatomical structures

We declare that the above medical device is in conformity with the following legislation(s):

Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices

The conformity of the quality management system according to Annex IX and Article 52 is certified by the following notified body:

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 IX and Article 52 to the above regulation is: 0123

Certificate number: G10 091596 0052

Reference to Common Specifications: /

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Relevant Harmonized Standard: EN IEC 63000:2018

Document number: 11647500 QCE 010 00

(related to STED 11647777 QCE 001)

Attachment to XP AA 4.4/19

Doc. ID of the template: MEAA4827718_19S ASD 10E 02

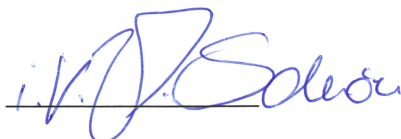
This declaration of conformity is issued under the sole responsibility of Siemens Healthcare GmbH.

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

Place and date Forchheim, 19.4.2023

Siemens Healthcare GmbH

Signature



Name

Dr. Verena Schön
Head of Business Line XP



Andreas Herdegen
Head of Quality Management XP

For conditions of warranty and liability please refer to the General Conditions of Sale.