Declaration of Conformity with Standards

Manufacturer	Siemens Medical Solutions USA, Inc. 22010 S.E. 51st Street Issaquah, WA 98029, USA
Single Registration Number (SRN)	Not yet available
Authorized Representative	Siemens Healthcare GmbH Henkestr. 127 91052 Erlangen Germany
Single Registration Number (SRN)	Not yet available
Facility	
Name:	Siemens Healthineers Ltd.
Address:	2nd~3rd Floor, 143, Sunhwan-ro, Jungwon-gu Seongnam-si, Gyeonggi-do, Republic of Korea

Product Identification

Product/Trade Name	ACUSON NX2 Elite™ Diagnostic Ultrasound System
Model	11284500
Basic UDI-DI	0405686900844VX
UDI-DI	04056869050775

Nomenclature Code

GMDN Code	40761
GMDN Term	Ultrasound system, imaging, general purpose
CND Code	Z11040101
CND Term	General Purpose Ultrasound Scanners

We declare the compliance of the above medical device with the standards listed on the following page(s).

Place and date: Issaquah, WA Feb. 16, 2021

Signature

Name: Khalil Thomas
Head of Quality Management, PRRC

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

Digitally signed by Belan Irina
Date: 2023.01.06 15:40:53 EET
Reason: MoldSign Signature
Location: Moldova

List of Standards

Reference No	Title of the standard
EN ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
ISO 9001: 2015	Quality management systems - Requirements;
ISO 14001:2015	Environmental management systems -- Requirements with guidance for use
EN 60601-1:2006 /A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 /A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard
EN 62366: 2008/A1:2015	Medical devices - Application of usability engineering to medical devices
EN 60601-2-18:2015	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
EN 60601-2-37:2008 /A1:2015	Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
EN 62359:2011	Ultrasonics – Field characterization – Test Methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008	Information to be supplied by manufacturer of medical devices
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
ISTA 2 Series	ISTA 2 Series: Partial Simulation Performance Tests. Procedure 2A(2011): Packaged-Products weighing 150 lb (68 kg) or Less Basic Requirements: atmospheric conditioning, compression, fixed displacement or random vibration and shock testing. Procedure 2B(2011): Packaged-Products weighing over 150 lb (68 kg) Basic Requirements: atmospheric conditioning, compression, fixed displacement or random vibration and shock testing
EN ISO 10993-1:2009 /AC:2010 and series	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 62304:2006 /AC:2008	Medical device software - Software life-cycle processes