

Certificate US19/819943682

The quality management system of

Sun Nuclear Corporation, also trading as Gammex, Inc.

7600 Discovery Drive, Middleton, WI, 53562, United States Of America

Facility Identification Number: F003964

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

MDSAP (ISO 13485:2016)

Australia:

Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Brazil Jurisdictions:

RDC ANVISA n. 16/2013 - Good Manufacturing Practices

RDC ANVISA n. 23/2012

RDC ANVISA n. 67/2009 - Vigilance

Canada:

Medical Devices Regulations – Part 1 SOR 98/282

United States:

21 CFR Part 803 - Medical Device Reporting

21 CFR Part 806 - Reports of Corrections and Removals

21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing

21 CFR Part 820 - Quality System Regulation

For the following activities and devices

Design, Manufacture, Distribution, Installation and Service of Anthropomorphic Phantoms, Quality Control Hardware and Software Devices, and Patient Positioning Laser Alignment Systems for the areas of Diagnostic Radiology and Radiation Oncology.

This certificate is valid from Effective Date: 15 August 2022 until Expiry Date: 27 March 2025 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 07 February 2025

Issue 3. Certified since 07 December 2019



Authorised by
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