

CERTIFICATEOF REGISTRATION

This is to certify that the management system of:

Sun Nuclear Corporation

(FIN F007120)

Main Site: 3275 Suntree Boulevard, Melbourne, Florida 32940 USA

Additional site1: 425A Pineda Ct., Melbourne, Florida, 32940, United States Additional site2: 415 Pineda Ct., Melbourne, Florida, 32940, United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Brazil: RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

Canada: Medical Devices Regulations - Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

Design, manufacture, installation, servicing and distribution of electronic dosimetry systems and radiotherapy QA software for the areas of radiation oncology and nuclear medicine.

Main site: Design and support of electronic dosimetry systems and radiotherapy QA software.

Additional site1: Warehousing, and distribution of electronic dosimetry systems and radiotherapy QA software

Additional site2: Receiving, manufacturing, installation, servicing of electronic dosimetry systems and radiotherapy QA software.

Organization was certified by another Certification Body before 5/9/2024.

Certificate Number:

0169459

Revision Level: 00

Initial Certification Date:

2020-04-27

Certification Effective Date:

2024-05-09

Certification Expiry Date:

2026-01-06



MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

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President, Business Assurance

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