

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 765326 R000

Manufacturer: Sun Nuclear Corporation

Address:

3275 Suntree Boulevard
Melbourne
Florida
32940
USA

Single Registration Number: US-MF-000020245

EU Authorised Representative: Sun Nuclear GmbH

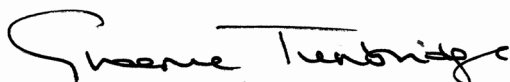
Address:

Gutenbergring 67A
Norderstedt
22848
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-09-26**

Current Issue Date: **2023-09-26**

Starting Validity Date: **2023-09-26**

Expiry Date: **2028-09-25**

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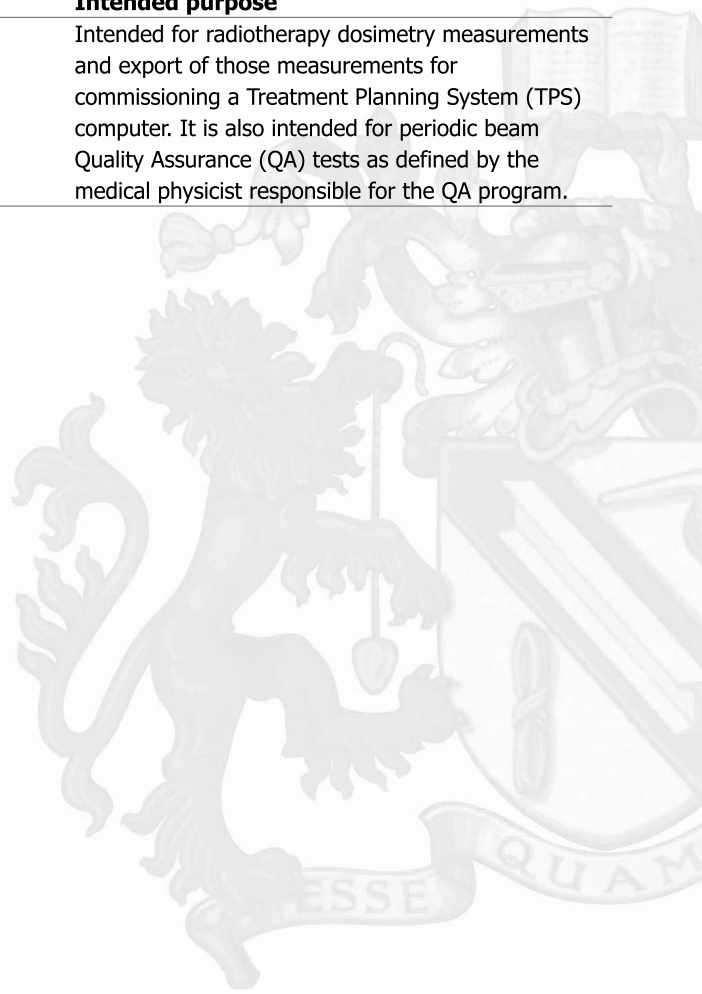
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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
SunSCAN 3D	Intended for radiotherapy dosimetry measurements and export of those measurements for commissioning a Treatment Planning System (TPS) computer. It is also intended for periodic beam Quality Assurance (QA) tests as defined by the medical physicist responsible for the QA program.



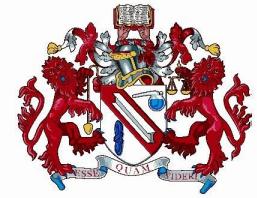
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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3618008	Issued



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.