SUN NUCLEAR
A MIRION MEDICAL COMPANY

Manufacturer's Declaration of Conformity

Sun Nuclear Corporation hereby declares under our sole responsibility that the class I product listed below is in conformity with the provision of Schedule 3 to the Australian therapeutic Goods (Medical Devices) Regulations of 2002, the European Medical Devices Directive 93/42/EEC (until 25 May 2021) and the European Medical Device Regulation 2017/745 (from May 26 2021), as well as 2015/863 on the restriction of hazardous substances in electrical and electronic equipment.

Manufacturer's Name:	Sun Nuclear Corporation
Manufacturer's Address:	7600 Discovery Drive Middleton Wisconsin 53562 United States
Manufacturer's SRN:	US-MF-000021541
EU Authorized Rep:	Sun Nuclear GmbH
Registrar:	SGS United Kingdom Ltd.
SGS Certificate:	US13/82774
Product Name:	Mammo 156 Phantom
Intended Purpose:	Radiological Quality Assurance
Model:	156
GMDN:	40609
Basic UDI DI:	++B136156GY
Assessment Route:	MDR 2017/745 Annex II, III

Standard Applied	Description
13485:2016	Medical Devices – Quality management systems – Requirements for regulatory purposes
14971:2019	Medical Devices – Application of risk management

This declaration was issued in Middleton, WI USA and is effective from 1 July 2022.

Authorized Signature: _____

Jeff Shaw, Director Regulatory Affairs