



DEVICE DETAILS

NAME OF DEVICE	IC Profiler
ESTABLISHMENT NAME	ONCORAY SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GA9896721-57342
BRAND NAME	Sun Nuclear
MEDICAL DEVICE CATEGORY	ELECTRO MECHANICAL MEDICAL DEVICES
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	The models 1122 and 1122-MR IC PROFILER are intended for quality assurance measurements of a radiation therapy beam from a radiotherapy treatment delivery device (TDD). The model 1122-MR is intended to operate in the magnetic field created by a TDD. Collected data is not intended for commissioning treatment planning systems or calibrating beam output
DEVICE INTENDED PURPOSE	The models 1122 and 1122-MR IC PROFILER are intended for quality assurance measurements of a radiation therapy beam from a radiotherapy treatment delivery device (TDD). The model 1122-MR is intended to operate in the magnetic field created by a TDD. Collected data is not intended for commissioning treatment planning systems or calibrating beam output
VALIDITY DATE OF REGISTRATION	22/03/2021 - 21/03/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	IC Profiler, Solid Water, Quad Wedge, and Accessories Storage Case	1122690
2	Gantry Mounting Fixture, Elekta Agility	1122000-EAZ
3	Gantry Mounting Fixture, Varian	1122000-VZ
4	Electron Energy Double Wedge Plate	1122602Z
5	Photon Energy Quad Wedge Plate	1122655Z
6	Electron Energy Quad Wedge Plate	1122656Z
7	Energy Verification Tools Set	1122664Z
8	Adapter plate for the GMF (1122000-V and 1122000-E)	1122-AZ
9	Solid Water HE 0.2cm	1174111Z

NO	NAME OF DEVICE	IDENTIFIER
10	Solid Water HE 0.3cm	1174112Z
11	Solid Water HE 0.5cm	1174113Z
12	Solid Water HE 1.0cm	1174114Z
13	Solid Water HE 2.0cm	1174115Z
14	Solid Water HE 5.0cm	1174116Z
15	Solid Water HE 3.0cm	1174117Z
16	Solid Water HE 4.0cm	1174118Z
17	IC PROFILER-MR	1122000-0MRZ
18	IC PROFILER Beam Scanning	1122000-0Z
19	Halcyon Acceptance Test Tools	1122000-PH
20	ICP SOLID WATER HE 35.3 x 36.7 x 2.0cm CHAMBER - A	805683
21	ICP SOLID WATER HE 35.3 x 36.7 x 2.0cm CHAMBER - B	805684
22	PF2 AND MC3 SOLID WATER HE 30.0 X 35.2 X 2.0 CHAMBER - A	805691
23	PF2 AND MC3 SOLID WATER HE 30.0 X 35.2 X 2.0 CHAMBER - B	805692

MEDICAL DEVICE AUTHORITY