EC CERTIFICATE

Cablon Medical BV

Klepelhoek 11, 3833 GZ Leusden
THE NETHERLANDS

Full Quality Assurance System
Approval Certificate

Annex II (excluding section 4) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:
Design and Manufacture of devices for real time radiotherapy imaging

Device Classifications:
Class IIb

Device Descriptions and Model Type:
Please refer to Attachment: 1

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC. Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with 1 attachment listing model numbers.

File Number	A18084	Cycle Start Date	March 8, 2018
Certificate Number	457.180306	Effective Date	March 6, 2018
Initial Issue Date	March 7, 2006	Expiry Date	March 7, 2023

Authorised by

Paul Daysh
Medical Notified Body Operations Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

Validate Certificate:
here

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

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Attachment 1 of 1

The products detailed below are covered under the scope of this certificate:

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Electronic Portal Imaging System	Theraview	Theraview Electronic Portal Imaging System	Class IIb	-
		Theraview TBI Imager	Class IIb	-

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