

UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

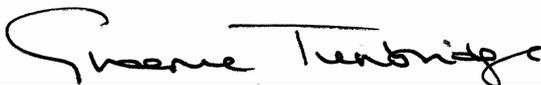
No. **UKCA 787692**
Issued To: **Intelerad Medical Systems Incorporated**
800 de Maisonneuve E
14th Floor
Montréal
Québec
H2L 4L8
Canada

In respect of:

Design, manufacture and final inspection of:
- Diagnostic Picture Archive and Communication System and Image viewing and processing software.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2023-04-19**

Date: **2023-09-18**

Expiry Date: **2025-03-31**

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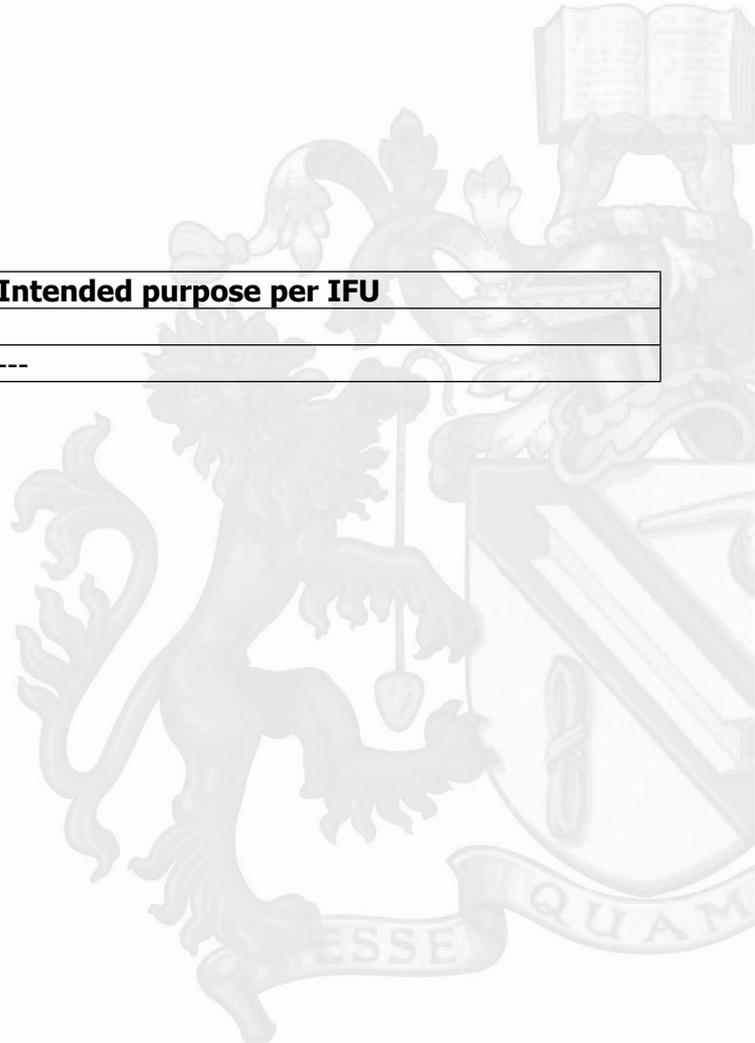
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Supplementary Information to UKCA 787692

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Number	Device Name	Intended purpose per IFU
Class IIa		
NBOG MD 1111	IntelePACS	---



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Certificate History

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 Canada

Date	Reference Number	Action
2023-04-19	3886555	First Issue; Traceable to CE 612569
Current	30001351	Change of legal manufacturer address from "800 Boulevard de Maisonneuve Est, 12ième étage, Montréal, Québec H2L 4L8 Canada" to "800 de Maisonneuve E 14th Floor, Montréal, Québec H2L 4L8 Canada"

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