By Royal Charter

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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Supplementary Information to UKCA 787692

Issued To:

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800 de Maisonneuve E
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Canada

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

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UKCA Certificate - Full Quality Assurance System Certificate History

Certificate No: **UKCA 787692**

Date: **2023-09-18**

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Québec
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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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Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000
Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.
A member of BSI Group of Companies.