

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]

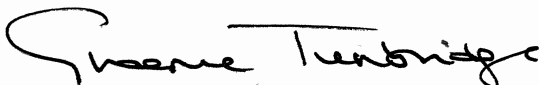
No. **UKCA 787692**
Issued To: **Intelerad Medical Systems Incorporated**
800 Boulevard de Maisonneuve Est
Montréal
12ième étage
Quebec
H2L 4L8
Canada

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: **2023-04-19**

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

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

This certificate was issued electronically and is bound by the conditions of the contract.

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.

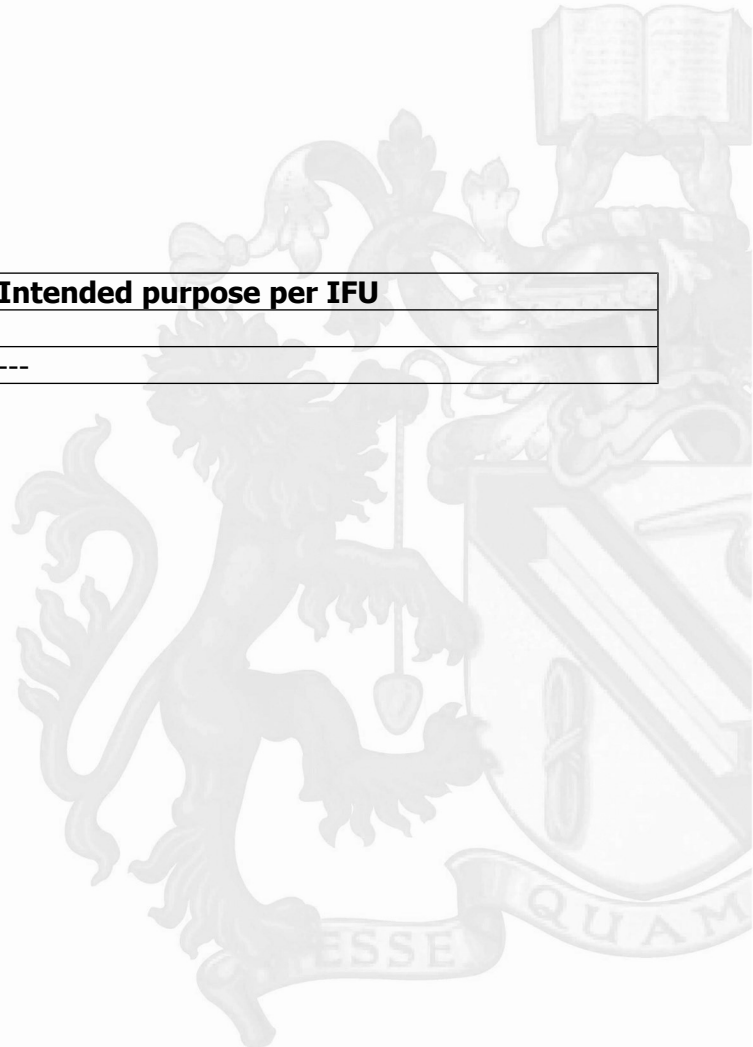
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Supplementary Information to UKCA 787692

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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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Date	Reference Number	Action
Current	3886555	First Issue; Traceable to CE 612569

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