EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 612569**

Issued To: **Intelerad Medical Systems Incorporated**
800 Boulevard de Maisonneuve East
12ième étage
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 Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2014-07-18** Date: **2020-04-01** Expiry Date: **2024-05-26**

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Supplementary Information to CE 612569

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Number	Device Name	Intended purpose per IFU
Class IIa		
NBOG MD 1111	IntelePACS	N/A

First Issued: **2014-07-18** Date: **2020-04-01** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 612569**

Date: **2020-04-01**

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Date	Reference Number	Action
18 July 2014	8134706	First issue, transfer from another Notified Body.
17 June 2016	8467524	Certificate renewal. Change of scope from "Design, manufacture, inspection and installation of Diagnostic Picture Archive and Communication System and Image viewing and processing software" to "Design, manufacture and final inspection of Diagnostic Picture Archive and Communication System and Image viewing and processing software".
25 January 2019	8861674	Traceable to NB 0086. Administrative wording update to subcontractor service from 'Inspection' to ' Final Inspection' for the following subcontractor: Intelerad Medical Systems.

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Date: **2020-04-01**

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Date	Reference Number	Action
21 October 2019	3085274	Legal manufacturer address changed from "895 de la Gauchetiere Street West, Suite 400, Montréal, Québec, H3B 4G1, Canada" to "800 Boulevard de Maisonneuve East, 12th Floor, Montreal, Quebec, H2L 4L8, Canada." EU Representative "Emergo Europe" address changed from "Molenstraat 15, 2513 BH, The Hague, Netherlands" to "Prinsessegracht 20, 2514 AP, The Hague Netherlands." Deletion of subcontractor, Intelerad Medical Systems Incorporated, 2350 Rue Cohen, Saint-Laurent, Quebec, H4R 2N6, Canada. Added product information table.
1 April 2020	9774162	Renewal.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
18 September 2023	30001459	Change of legal manufacturer address. Change of EU Representative address.

Inspiring trust for a more resilient world.

18 September 2023

Intelerad Medical Systems Incorporated
800 de Maisonneuve E 14 Floor
Montréal
Québec
H2L 4L8
Canada

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	**Directive and Annex**	**Reference Number**	**Changes approved**
CE 612569	93/42/EEC Annex II excluding Section 4	30001459	Change of legal manufacturer address from "800 Boulevard de Maisonneuve Est, 12ième étage, Montréal, Québec H2L 4L8 Canada" to "800 de Maisonneuve E 14 Floor, Montréal, Québec H2L 4L8 Canada" Change of EU Representative address.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices