

EC Certificate - Full Quality Assurance System

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

No. CE 708330
Issued To: **Institut de diagnostic per la imatge IDI**
Parc Sanitari Pere Virgili,
Edifici Mestral planta 2,
C/ Esteve Terradas 30
Barcelona
08023
Spain

In respect of:

Design and manufacture of radiology DICOM image processing application 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: **2020-03-13**

Date: **2020-03-13**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

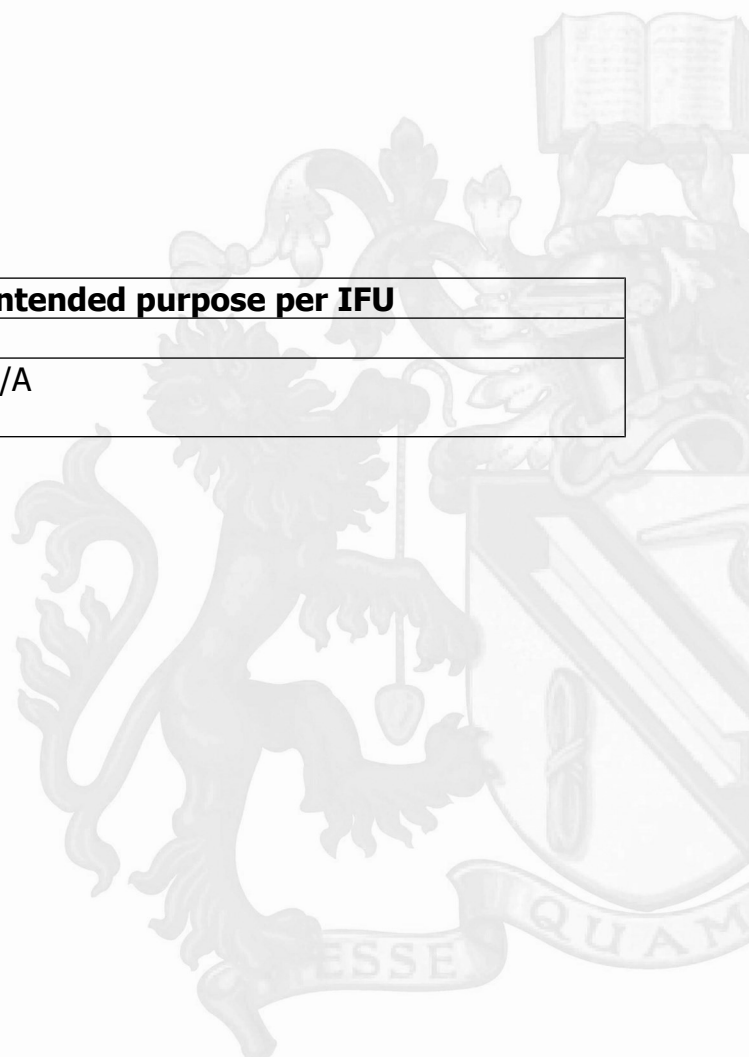
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Supplementary Information to CE 708330

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Number	Device Name	Intended purpose per IFU
Class IIa		
NBOG MD 1111	Starviewer Medical Imaging Software	N/A



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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	Service(s) supplied
Universitat de Girona Escola Politècnica Superior Campus Montilivi, Edifici P4 Girona 17003 Spain	Software

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 708330**
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Date	Reference Number	Action
Current	9737061	First issue.

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