

EC Certificate - Full Quality Assurance System

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

No. CE 684406
Issued To: **Synopsys (Northern Europe) Ltd**
Bradninch Hall, Castle Street
Exeter
Devon
EX4 3PL
United Kingdom

In respect of:

Design and manufacture of Software interface & segmentation system for use with medical images; pre-operative software for pre-surgical simulation.

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: **2018-12-11**

Date: **2020-12-17**

Expiry Date: **2023-12-10**

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Page 1 of 2

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.

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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Supplementary Information to CE 684406

Issued To:

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1111	Simpleware ScanIP Medical	<p>Intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging scanner to an output file.</p> <p>Also intended as pre-operative software for simulating/evaluating surgical treatment options.</p> <p>ScanIP is not intended to be used for mammography imaging.</p>

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Page 2 of 2

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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

Synopsys International Limited
Blanchardstown Corp Park
Block 1
Dublin 15
Ireland

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 684406**
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Date	Reference Number	Action
11 December 2018	8859941	First Issue.
21 February 2019	8859950	Traceable to NB 0086.
Current	3339543	Certificate update for addition of EU Representative, Synopsys International Limited, Blanchardstown Corp Park, Block 1, Dublin 15, Ireland and change in device name from Simpleware ScanIP to Simpleware ScanIP Medical.