By Royal Charter

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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Supplementary Information to CE 684406

Issued To:

Synopsys (Northern Europe) Ltd
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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1111	Simpleware ScanIP Medical	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. Also intended as pre-operative software for simulating/evaluating surgical treatment options. ScanIP is not intended to be used for mammography imaging.

First Issued: **2018-12-11** Date: **2020-12-17** Expiry Date: **2023-12-10**

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List of Significant Subcontractors

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

Certificate No:	**CE 684406**
Date:	**2020-12-17**
Issued To:	**Synopsys (Northern Europe) Ltd** **Bradninch Hall, Castle Street** **Exeter** **Devon** **EX4 3PL** **United Kingdom**

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**

Date: **2020-12-17**

Issued To: **Synopsys (Northern Europe) Ltd**
Bradninch Hall, Castle Street
Exeter
Devon
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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.