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

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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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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 684406**

Date: **2020-12-17**

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Date	Reference Number	Action
11 December 2018	8859941	First Issue.
21 February 2019	8859950	Traceable to NB 0086.
17 December 2020	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.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
11 September 2024	30244664	Change of EU Authorised Representative Address Removal of subcontractors

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11 September 2024

Synopsys (Northern Europe) Ltd
Bradninch Hall, Castle Street
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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 684406	93/42/EEC Annex II excluding Section 4	30244664	Change of EU Authorised Representative Address Removal of subcontractors

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