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
Bradninch Hall, Castle Street
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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
EX4 3PL
United Kingdom

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.

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Synopsys (Northern Europe) Ltd
Bradninch Hall, Castle Street
Exeter
Devon
EX4 3PL
United Kingdom

22 November 2023

Notified Body Confirmation Letter

Reference: EU2023-607/732439

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Synopsys (Northern Europe) Ltd
Bradninch Hall, Castle Street
Exeter
United Kingdom

SRN Number: GB-MF-000002376

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Simpleware Medical	Class IIa	Simpleware ScanIP Medical	Certificate CE 684406 NB 2797

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2022/11/22	Initial issue
2024/06/05	Amended – Change of device name to Simpleware Medical