EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 774091 R000

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Manufacturer: Synopsys (Northern Europe) Ltd.

Address:
Bradninch Hall
Castle Street
Exeter
Devon
EX4 3PL
United Kingdom

Single Registration Number: GB-MF-000002376

EU Authorised Representative: Synopsys International Ltd.

Address:
Blanchardstown Corp Park
Block 1
Dublin 15
Ireland

Scope: See attached Device Schedule

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: 2024-02-28

First Issue Date: 2024-02-28

Current Issue Date: 2024-06-05

Current Issue Date: 2024-06-05

Starting Validity Date: 2024-06-05

Starting Validity Date: 2024-06-05

Expiry Date: 2029-02-27

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Simpleware Medical	Class IIa

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