

EU Quality Management System Certificate

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

MDR 737603 R000

Manufacturer: 3Shape TRIOS A/S

Address:

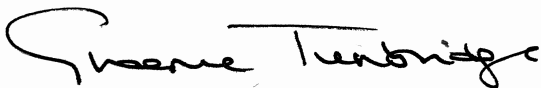
Holmens Kanal 7
Copenhagen
1060
Denmark

Single Registration Number: DK-MF-000001218

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 and Class IIb implantable devices an 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 Medical Devices

First Issued: **2022-07-08**

Date: **2022-07-08**

Expiry Date: **2027-07-07**

...making excellence a habit.™

Page 1 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

EU Quality Management System Certificate

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

MDR 737603 R000

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

Device(s)	Risk Classification
TRIOS Patient Monitoring	Class IIa



First Issued: **2022-07-08**

Date: **2022-07-08**

Expiry Date: **2027-07-07**

...making excellence a habit.™

EU Quality Management System Certificate

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

MDR 737603 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3308140	Issued



First Issued: **2022-07-08**

Date: **2022-07-08**

Expiry Date: **2027-07-07**

...making excellence a habit.™

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

EU Quality Management System Certificate

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

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 737603 R000

Date: 2022-07-08

Critical Subcontractor/Crucial Supplier	Service(s) supplied
3Shape Dooel Skopje Kole Nedelkovski No.11 1000 Skopje Republic of North Macedonia	Software
3Shape Ukraine LLC Kazymyra Malevycha str., 86 Kyiv 03150 Ukraine	Software
3Shape Ukraine LLC Polova str, 21 "Lahoda" Business Centre, Building B Kyiv 03056 Ukraine	Software

...making excellence a habit.™