By Royal Charter

EU Quality Management System Certificate

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

MDR 729828 R000

Manufacturer: OrbusNeich Medical, B.V.

Address:
Drs. W. van Royenstraat 5
3871 AN Hoevelaken
The Netherlands

Single Registration Number: NL-MF-000010907

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):

[redacted] & Quality

First Issue Date: **2023-04-26**

Current Issue Date: **2024-12-12**

Starting Validity Date: **2024-12-12**

Expiry Date: **2028-04-25**

...making excellence a habit.™

EU Quality Management System Certificate

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

MDR 729828 R000

Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
COMBO Bio-engineered Sirolimus Eluting Stent COMBO Plus Dual Therapy Stent	See MDR 763106

Class III	Intended purpose
Xtenza Guide Catheter Extension	See MDR 776478
Sapphire II NC Coronary Dilatation Catheter Sapphire II PRO Coronary Dilatation Catheter Sapphire NC 24 Coronary Dilatation Catheter Sapphire 3 Coronary Dilatation Catheter	See MDR 776477
Scoreflex NC Coronary Dilatation Catheter	See MDR 776476
Scoreflex TRIO Balloon Dilatation Catheter	See MDR 763109
Teleport Microcatheter	See MDR 763110
Teleport XT Microcatheter	See MDR 776475

First Issue Date: **2023-04-26**

Current Issue Date: **2024-12-12**

Starting Validity Date: **2024-12-12**

Expiry Date: **2028-04-25**

...making excellence a habit.™

EU Quality Management System Certificate

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

MDR 729828 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
2023-04-26	3218820	Issued.
2023-05-25	3912281	Supplemented - Addition of Teleport Microcatheter and Scoreflex TRIO Balloon Dilatation Catheter to device schedule
2023-06-19	30000509	Amended - Administrative update to prior history entry reference number 3912281. Supplemented - Addition of EZGuide Guide Catheter Extension to device schedule.
2023-07-31	30001718	Supplemented – Addition of Scoreflex NC Coronary Dilatation Catheter to device schedule.
2024-03-18	30091596	Amended – Administrative update to Class III device schedule; device listing alphabetized. Administrative correction to legal manufacturer name format. Supplemented – Addition of COMBO Bio-engineered Sirolimus Eluting Stent and COMBO Plus Dual Therapy Stent to device Schedule.
2024-11-08	30251140	Amended - Device trade name change from EZGuide Guide Catheter Extension to Xtenza Guide Catheter Extension.
Current	30298132	Supplemented – Addition of Teleport XT Microcatheter

First Issue Date: **2023-04-26**

Current Issue Date: **2024-12-12**

Starting Validity Date: **2024-12-12**

Expiry Date: **2028-04-25**

...making excellence a habit.™