EC Declaration of Conformity

Sapphire NC 24 Coronary Dilatation Catheter

Product Name	:	Sapphire NC 24 Coronary Dilatation Catheter
Classification	:	Class III (MDD Annex IX)
Conformity Assessment	:	MDD 93/42/EEC, Annex II

Manufacturer:	Name:	OrbusNeich Medical (Shenzhen) Co., Ltd.
	Address:	No. 1 Jinkui Road Futian Free Trade Zone Shenzhen 518038 China
EU Authorized Representative:	Name:	Quality First International OÜ
	Address:	Laki 30 12915 Tallinn Estonia
Notified Body:	Name:	BSI
	Address:	Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
Certificates:		EC Certificate No.: CE 619984 EC Design Examination Certificate No. : CE 706141
General Applicable Directives		Medical Device Directive: Council Directive 93/42/EEC of June 14th, 1993 concerning medical devices (MDD 93/42/EEC)

We hereby declare that the distributed CE marked products, as specified on the attached product schedule, are covered by the "CE Marking of Conformity Certificate", and delivered by Notified Body "BSI", Notified Body Identification Number: 2797. All products on the attached schedule meet the provisions of the abovementioned EC Council Directives, and conform to the required technical documentation, in accordance with Annex II of the "EC-Directive", the "Council Directive 93/42/EEC of 14 June 1993, concerning medical devices".

This declaration is based on the application of the Quality System approved for the design manufacture and final inspection of the products concerned, in accordance with Annex II (Full quality assurance system) of the Council Directive 93/42/EEC. The conformity of the production quality assurance set out in Annex II, is confirmed in the said CE Marking of Conformity Certificate, issued and delivered by BSI.

All supporting documentation, in evidence to the above, is retained on the premises of the manufacturer.

Authorized Representative: Sandra Li

Title: Director of Quality

Signature: Sandra

Place & Date: Shenzhen Apr 20, 2020

Product Schedule:

Sapphire NC 24 Coronary Dilatation Catheter		
Catalog Number	***Balloon* Diameter (mm)**	***Balloon* Length (mm)**
215-084-5J	1.5	8
215-104-5J	1.5	10
215-124-5J	1.5	12
215-154-5J	1.5	15
215-184-5J	1.5	18
215-224-5J	1.5	22
215-264-5J	1.5	26
217-084-5J	1.75	8
217-104-5J	1.75	10
217-124-5J	1.75	12
217-154-5J	1.75	15
217-184-5J	1.75	18
217-224-5J	1.75	22
217-264-5J	1.75	26
220-084-5J	2.0	8
220-104-5J	2.0	10
220-124-5J	2.0	12
220-154-5J	2.0	15
220-184-5J	2.0	18
220-224-5J	2.0	22
220-264-5J	2.0	26
222-084-5J	2.25	8
222-104-5J	2.25	10
222-124-5J	2.25	12
222-154-5J	2.25	15
222-184-5J	2.25	18
222-224-5J	2.25	22
222-264-5J	2.25	26
225-084-5J	2.5	8
225-104-5J	2.5	10
225-124-5J	2.5	12
225-154-5J	2.5	15
225-184-5J	2.5	18
225-224-5J	2.5	22
225-264-5J	2.5	26
227-084-5J	2.75	8
227-104-5J	2.75	10
227-124-5J	2.75	12
227-154-5J	2.75	15
227-184-5J	2.75	18

227-224-5J	2.75	22
227-264-5J	2.75	26
228-084-5J	2.875	8
228-104-5J	2.875	10
228-124-5J	2.875	12
228-154-5J	2.875	15
228-184-5J	2.875	18
228-224-5J	2.875	22
228-264-5J	2.875	26
230-084-5J	3.0	8
230-104-5J	3.0	10
230-124-5J	3.0	12
230-154-5J	3.0	15
230-184-5J	3.0	18
230-224-5J	3.0	22
230-264-5J	3.0	26
232-084-5J	3.25	8
232-104-5J	3.25	10
232-124-5J	3.25	12
232-154-5J	3.25	15
232-184-5J	3.25	18
232-224-5J	3.25	22
232-264-5J	3.25	26
235-084-5J	3.5	8
235-104-5J	3.5	10
235-124-5J	3.5	12
235-154-5J	3.5	15
235-184-5J	3.5	18
235-224-5J	3.5	22
235-264-5J	3.5	26
237-084-5J	3.75	8
237-104-5J	3.75	10
237-124-5J	3.75	12
237-154-5J	3.75	15
237-184-5J	3.75	18
237-224-5J	3.75	22
237-264-5J	3.75	26
240-084-5J	4.0	8
240-104-5J	4.0	10
240-124-5J	4.0	12
240-154-5J	4.0	15
240-184-5J	4.0	18
240-224-5J	4.0	22

240-264-5J	4.0	26
245-084-5J	4.5	8
245-104-5J	4.5	10
245-124-5J	4.5	12
245-154-5J	4.5	15
245-184-5J	4.5	18
245-224-5J	4.5	22
245-264-5J	4.5	26
250-084-5J	5.0	8
250-104-5J	5.0	10
250-124-5J	5.0	12
250-154-5J	5.0	15
250-184-5J	5.0	18
250-224-5J	5.0	22
250-264-5J	5.0	26

SAPPHIRE II PRO Coronary Dilatation Catheter

CORONARY DILATATION CATHETER

INSTRUCTIONS FOR USE

ENGLISH

CE 2797

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.
OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS.
FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

DEVICE DESCRIPTION

The Sapphire II PRO Coronary Dilatation Catheter is designed to allow easy exchange of the catheter using a standard length 0.014 inch guidewire. Balloon diameters range from 1.0mm to 4.0mm. The balloon is made of the semi-compliant material, 1.0mm to 1.5mm balloons have a rated burst pressure of 16 atmospheres and 1.75mm to 4.0mm balloons have a rated burst pressure of 14 atmospheres. The proximal shaft of the catheter is composed of a female luer connector bonded to a PTFE coated stainless steel tube. The proximal shaft allows superior proximal pushability with a smooth transition to a distal shaft composed of an outer tube, an inner tube and a balloon. Two radiopaque platinum/iridium marker bands are located within the balloon segment with the exception of 1.0mm to 1.5mm balloons which incorporate a centrally positioned single marker band. The guidewire enters the catheter tip and advances coaxially out the distal Rx port, thereby allowing both coaxial guidance and rapid exchange of catheter with a single standard length guidewire. Two marker sections of 5mm length each located on the proximal shaft indicate catheter position relative to the tip of either a brachial or femoral guiding catheter. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements.

HOW SUPPLIED

Contents	One (1) Sapphire II PRO Coronary Dilatation catheter, one (1) Re-wrap tool, one (1) securement clip, one (1) flushing needle.
Sterile	Sterilized with ethylene oxide gas. Non-pyrogenic. Do not use if the package is open or damaged.
Storage	Store in a dry, dark, cool place.

INDICATIONS

For balloon dilatation of a stenotic portion of a coronary artery in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.

CONTRAINDICATIONS

The use of the Sapphire II PRO Coronary Dilatation Catheter is contraindicated in the following patient types:

- Patients with an unprotected left main coronary artery
- Patients with coronary artery spasm in the absence of a significant stenosis

WARNINGS

When using this type of device, the following warnings should be observed:

- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery require careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.
- When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the rated burst pressure (RBP) indicated on the package. The RBP is based on results of *in vitro testing*. Use of a pressure monitoring device is recommended to prevent over pressurization.
- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- Use the catheter prior to the "Use By" date specified on the package.
- This device is designed and intended for single use only. DO NOT reprocess, resterilize and/or reuse. Reuse of single-use devices creates a potential risk of patient or user infections. Reuse may lead to impairment of functional performance. Infections and/or limited performance of the device may lead to injury, illness or death of the patient.

PRECAUTIONS

- Do not reinsert the PTCA catheter into the coil dispenser after procedural use.
- Prior to angioplasty, the dilatation catheter should be examined to verify functionality and ensure that its size is suitable for the specific procedure for which it is being used.
- The catheter system should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty.
- During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. After the procedure, anticoagulant therapy should be continued for a period of time as determined by the physician.
- The design and construction of these catheters do not provide the user with distal pressure monitoring capability.
- Discard all disposable devices used during this procedure per local requirements for medical device waste disposal.
- Do not use oil-based contrast medium, organic solvents or alcohols; there is a possibility of catheter leak, damage or lubrication loss.

POTENTIAL COMPLICATIONS AND ADVERSE EFFECTS

Potential complications and adverse effects due to the use of this product include, but are not limited to, the following:

- Death
- Acute myocardial infarction
- Total occlusion of the coronary artery
- Coronary vessel dissection, perforation, rupture or injury
- Restenosis of the dilated vessel
- Unstable angina
- Arrhythmias, including ventricular fibrillation
- Drug reactions, allergic reaction to contrast medium
- Hypo/hypertension
- Infection
- Coronary artery spasm
- Arteriovenous fistula
- Embolism
- Balloon burst due to lesion characteristics

MATERIALS REQUIRED

- Arterial Sheath
- Femoral or brachial guiding catheter in the appropriate size and configuration
- Hemostatic valve(s)
- Contrast medium diluted 1:1 with normal saline
- Sterile heparinized normal saline
- 20 cc Luer-lock syringe
- Inflation device
- Guidewire diameter not to exceed 0.014"; see product label
- Guidewire introducer
- Guidewire torque device

PREPARATION FOR USE

Prior to use, examine all equipment carefully for defects. Examine the dilatation catheter for bends, kinks, or other damage. Do not use any defective equipment.
Prepare equipment to be used following manufacturer's instructions or standard procedure.
Complete the following steps to prepare the PTCA catheter for use:

1. Remove the protective mandrel from the catheter tip.
2. Slide the protective sheath off the balloon.
3. Flush the guidewire lumen of the PTCA catheter.
4. Attach the syringe with heparinized normal saline to the flushing needle packaged with the catheter; gently insert the needle into the tip of the catheter and flush the guidewire lumen with heparinized normal saline until fluid is seen exiting the guidewire port.
5. Prepare an inflation device with the recommended contrast medium according to the manufacturer's instructions.
6. Evacuate air from the balloon segment using the following procedure:
7. Fill a 20 cc syringe or the inflation device with approximately 4 cc of the recommended contrast medium.
8. After attaching the syringe or inflation device to the balloon inflation lumen, orient the dilatation catheter with the distal tip and the balloon pointing in a downward vertical position.
9. Apply negative pressure and aspirate for 15 seconds. Slowly release the pressure to neutral, allowing contrast to fill the shaft of the dilatation catheter.
10. Disconnect the syringe or inflation device from the inflation port of the dilatation catheter.
11. Remove all air from the syringe or inflation device barrel. Reconnect the syringe or inflation device to the inflation port of the dilatation catheter. Maintain negative pressure on the balloon until air no longer returns to the device.
12. Slowly release the device pressure to neutral.
13. Disconnect the 20 cc syringe (if used) and connect the inflation device to inflation port of the dilatation catheter without introducing air into the system.

Caution: All air must be removed from the balloon and displaced with contrast prior to inserting into the body. Otherwise complications may occur.

INSTRUCTIONS FOR USE

1. Insert a guidewire through the hemostatic valve that is on the guiding catheter, following the manufacturer's instructions.
2. Advance the guidewire carefully into and through the guiding catheter. Withdraw the guidewire introducer, if used.
3. Attach a torque device to the guidewire, if desired. Under fluoroscopy, proceed with accepted PTCA techniques to advance the guidewire to and across the lesion.
4. Backload the distal tip of the dilatation catheter onto the guidewire ensuring that guidewire exits the catheter at approximately 25 cm proximal to the balloon.
5. Advance the dilatation catheter over the guidewire until it approaches the hemostatic valve.
6. Open the hemostatic valve. Insert the dilatation catheter while maintaining guidewire position and tighten the hemostatic valve. To facilitate insertion, the balloon must be fully deflated to negative pressure.
7. Tighten the hemostatic valve to create a seal around the dilatation catheter without inhibiting movement of the dilatation catheter. This will allow continuous recording of proximal coronary artery pressure.

Note: It is important that the hemostatic valve be closed tightly enough to prevent blood leakage around the dilatation catheter shaft, yet not so tight that it restricts the flow of contrast into and out of the balloon or restricts guidewire movement.

8. Advance the dilatation catheter until the appropriate proximal marker aligns with the hemostatic valve hub. This indicates that the dilatation catheter tip has reached the guiding catheter tip.
9. Advance the dilatation catheter over the guidewire and into the stenosis. Continue under fluoroscopy and use the radiopaque marker band(s) to position the usable (dilating) section of the balloon within the stenosis.

Note: When using the dual wire technique, a dual hemostatic valve should be used and care taken when introducing, torquing and removing one or both wires to avoid entanglement. Guidewires should not be rotated more than 180 degrees in either direction during the dual wire procedure. It is recommended that one wire be completely withdrawn from the patient before removing additional equipment.
Caution: If any resistance is felt, do not advance the guidewire or the dilatation catheter by force. Before proceeding, determine the cause under high resolution fluoroscopy. Advancement by force may result in damage to the vessel and/or laceration or separation of the guidewire or the dilatation catheter. This may necessitate recovery of fragments.

10. Continue the procedure using accepted coronary angioplasty technique to dilate the stenosis. Note: Do not exceed the rated burst pressure printed on the package label. Maintain negative pressure on the balloon between inflations.

Caution: The balloon may slip out of the lesion when inflated because of the hydrophilic coating. Inflate the balloon carefully under the guidance of high resolution fluoroscopy so that the balloon does not change position in the lesion.

11. Withdraw the deflated PTCA catheter and guidewire into the guiding catheter. Using a technique of choice, remove the PTCA catheter, guidewire and guiding catheter from the vasculature. Discard the PTCA catheter, guidewire, and guiding catheter.

Caution: Removal of the dilatation catheter should be done after loosening the hemostatic valve.

12. The catheter may be coiled once using the securement clip provided in the package (attached to the bottom left of the compliance card). Care should be taken not to kink or bend the shaft upon placement or removal of the clip. Only the proximal shaft should be secured with the securement clip; it is not intended for the distal end of the catheter.
13. The balloon may be re-folded once (after expansion) using the balloon re-wrap tool provided in the package (attached to the upper right of the compliance card). The stylet should be used concurrently to support the guidewire lumen and care should be taken not to damage the balloon upon placement or removal of the re-wrap tool.

EXCHANGE PROCEDURE TECHNIQUE

The PTCA catheter has been specifically designed for rapid, single operator balloon exchanges. To perform a dilatation catheter exchange:

1. Loosen the hemostatic valve.
2. Hold the guidewire and hemostatic valve in one hand, while grasping the balloon shaft in the other hand.
3. Maintain guidewire position in the coronary artery by holding the wire stationary, and begin pulling the dilatation catheter out of the guiding catheter while monitoring the wire position under fluoroscopy.
4. Withdraw the deflated dilatation catheter until the guidewire lumen is reached. Carefully pull back the flexible, distal portion of the dilatation catheter out of the rotating hemostatic valve while maintaining the guidewire's position across the lesion.
5. Slide the distal tip of the dilatation catheter out of the hemostatic valve, and tighten valve onto the guidewire to hold it securely in place.
6. Prepare the next dilatation catheter to be used, as previously described in the Preparation For Use section.
7. Back load another dilatation catheter onto the guidewire as previously described under the Instructions For Use Section, Step 4, and continue the procedure accordingly.

REFERENCES

The physician should consult recent literature on current medical practice on balloon dilatation, such as that published by ACC/AHA.

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

Descriptions or specifications in OrbusNeich Medical printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties. OrbusNeich Medical will not be responsible for any direct, incidental, or consequential damages resulting from the misuse of the product.

OrbusNeich Medical (Shenzhen) Co., Ltd
1 Jinkui Road
Futian Free Trade Zone
Shenzhen 518038
China

EC REP
Quality First International OÜ
Laki 30
12915 Tallinn
Estonia

EXPLANATION OF SYMBOLS

Description	Symbol
Catalog Number	REF
Lot Number	LOT
Balloon Diameter	BALLOON ⌀
Balloon Length	BALLOON ⊢ ⊣
Sterilized Using Ethylene Oxide	STERILE EO
Use By	
Do Not Reuse	
Caution	
Consult Instructions For Use	
Do Not Resterilize	
Guiding Catheter	
Contents (numeral represents quantity of units inside)	1
Keep Dry	
Keep Away from Sunlight / Heat	
EU Authorized Representative	EC REP
Manufacturer	
Conformity to the Council Directive 93/42/EEC Concerning Medical Devices	CE 2797

OrbusNeich

www.OrbusNeich.com

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 619984**

Issued To: **OrbusNeich Medical (Shenzhen) Co., Ltd**
No.1 Jinkui Road
Futian Free Trade Zone
Shenzhen
China

In respect of:

Design, manufacture and final inspection of sterile intravascular catheters.

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: **2015-02-03** Date: **2021-04-19** Expiry Date: **2023-04-20**

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Supplementary Information to CE 619984

Issued To:

OrbusNeich Medical (Shenzhen) Co., Ltd
No.1 Jinkui Road
Futian Free Trade Zone
Shenzhen
China

NBOG code(s)	Device Name	Intended purpose per IFU
Class III		
MD 0106	Sapphire NC 24 Coronary Dilatation Catheter	See CE 706141
MD 0106	Sapphire 3 Coronary Dilatation Catheter	See CE 712825
MD 0106	Sapphire II PRO Coronary Dilatation Catheter	See CE 619994
MD 0106	Scoreflex NC Coronary Dilatation Catheter	See CE 646778
MD 0106	Sapphire II NC Coronary Dilatation Catheter	See CE 649483
MD 0106	Sapphire II (RX) Coronary Dilatation Catheter	See CE 649487
MD 0106	Teleport Microcatheter	See CE 673072

First Issued: **2015-02-03** Date: **2021-04-19** Expiry Date: **2023-04-20**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 619984

Issued To:

OrbusNeich Medical (Shenzhen) Co., Ltd
No.1 Jinkui Road
Futian Free Trade Zone
Shenzhen
China

NBOG code(s)	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	JADE PTA Balloon Dilatation Catheter	---
MD 0106	Scoreflex PTA Balloon Dilatation Catheter	---

First Issued: **2015-02-03** Date: **2021-04-19** Expiry Date: **2023-04-20**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 619984**
Date:	**2021-04-19**
Issued To:	**OrbusNeich Medical (Shenzhen) Co., Ltd** **No.1 Jinkui Road** **Futian Free Trade Zone** **Shenzhen** **China**

Subcontractor:	**Service(s) supplied**
Quality First International OÜ Laki 30 12915 Tallinn Estonia	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 619984**

Date: **2021-04-19**

Issued To: **OrbusNeich Medical (Shenzhen) Co., Ltd**
No.1 Jinkui Road
Futian Free Trade Zone
Shenzhen
China

Date	Reference Number	Action
03 February 2015	8224623	First issue.
04 June 2015	8224638	Update scope to reflect introducer sheaths and add product names on page 2.
31 July 2015	8330084	Add JADE PTA and Scoreflex PTA Balloon Dilatation Catheters to listed product families.
12 May 2016	8451210	Add Scoreflex NC to listed product families.
22 June 2016	8558739	Add Sapphire II PRO PTA Balloon Dilatation Catheter to listed product families.
19 May 2017	8481875	Add Sapphire II NC Coronary Dilatation Catheter and Sapphire II (RX) Coronary Dilatation Catheter to listed product families; transfer from another notified body.
05 March 2018	8729966	Addition of Teleport Microcatheter to listed product families.
18 April 2018	8729034	Certificate Renewal.
08 March 2019	8250492	Traceable to NB 0086.
06 September 2019	9784370	Change of EU Representative Address. Administrative change to product table.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 619984**

Date: **2021-04-19**

Issued To: **OrbusNeich Medical (Shenzhen) Co., Ltd**
No.1 Jinkui Road
Futian Free Trade Zone
Shenzhen
China

Date	Reference Number	Action
26 March 2020	3151775	Update device table to include Sapphire NC 24 and Sapphire 3 Coronary Dilatation Catheters.
Current	3393509	Reduction of scope to remove introducer sheaths. Clarification of scope to include 'final inspection' and remove 'development'. Update to products table in supplementary information section to remove Advance Pro Catheter Sheath Introducer System and Sapphire II PRO PTA Balloon Dilatation Catheter. Correction to EU Representative address.

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 619995**

Issued To: **OrbusNeich Medical B.V.**
Drs. W.van Royenstraat 5
3871 AN Hoevelaken
The Netherlands

In respect of:

Design, development, manufacture of sterile intravascular catheters, coronary stents and drug-eluting coronary stents.

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: **2015-02-03** Date: **2021-04-19** Expiry Date: **2023-04-21**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 619995

Issued To:

OrbusNeich Medical B.V.
Drs. W.van Royenstraat 5
3871 AN Hoevelaken
The Netherlands

NBOG code(s)	Device Name	Intended purpose per IFU
Class III		
MD 0106	Sapphire NC 24 Coronary Dilatation Catheter	See CE 706144
MD 0106	Sapphire 3 Coronary Dilatation Catheter	See CE 712118
MD 0106	Sapphire II PRO Coronary Dilatation Catheter	See CE 620000
MD 0106	Scoreflex NC Coronary Dilatation Catheter	See CE 646780
MD 0201 MDS 7001 MDS 7002	Combo Bio-Engineered Sirolimus Eluting Stent (Combo Stent)	See CE 649477
MD 0106	ScoreFlex Coronary Dilatation Catheter	See CE 649479
MD 0106	Sapphire NC Coronary Dilatation Catheter	See CE 649480
MD 0106	Sapphire Coronary Dilatation Catheter	See CE 649482
MD 0106	Sapphire II NC Coronary Dilatation Catheter	See CE 649484

First Issued: **2015-02-03** Date: **2021-04-19** Expiry Date: **2023-04-21**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 619995

Issued To:

OrbusNeich Medical B.V.
Drs. W.van Royenstraat 5
3871 AN Hoevelaken
The Netherlands

NBOG code(s)	Device Name	Intended purpose per IFU
Class III		
MD 0106	Sapphire II (RX) Coronary Dilatation Catheter	See CE 649488
MD 0201	Azule CoCr Alloy Coronary Stent Delivery System	See CE 649490
MD 0201 MDS 7001 MDS 7002	COMBO Plus Dual Therapy Stent (COMBO Plus Stent)	See CE 649589
MD 0106	Teleport Microcatheter	See CE 673071
Class IIa		
MD 0106	JADE PTA Balloon Dilatation Catheter	---
MD 0106	Scoreflex PTA Balloon Dilatation Catheter	---

First Issued: **2015-02-03** Date: **2021-04-19** Expiry Date: **2023-04-21**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 619995**
Date:	**2021-04-19**
Issued To:	**OrbusNeich Medical B.V.** **Drs. W.van Royenstraat 5** **3871 AN Hoevelaken** **The Netherlands**

Subcontractor:	**Service(s) supplied**
Chunghwa Chemical Synthesis & Biotech Co., Ltd 1,Tung-Hsing St. Shu-Lin New Taipei City 23850 Taiwan	**Crucial Supplier**
Fujian Kerui Pharmaceutical Co., Ltd. Yuanzai Industrial Area Fujian Province, 350313 China	**Crucial Supplier**
Goodwin Biotechnology, Inc. 1850 NW 69th Ave Plantation, FL 33313 USA	**Crucial Supplier**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 619995**
Date:	**2021-04-19**
Issued To:	**OrbusNeich Medical B.V.** **Drs. W.van Royenstraat 5** **3871 AN Hoevelaken** **The Netherlands**

Subcontractor:	**Service(s) supplied**
MeKo Laserstrahl-Materialbearbeitungen Im Kirchenfelde 12-14 Hannover D-31157 Sarstedt Germany	**Manufacture**
OrbusNeich Medical (Shenzhen) Co., Ltd. No. 1 Jinkui Road Futian Free Trade Zone Shenzhen 518038 China	**Design** **Manufacture**
Patheon Biologics B.V. Zuiderweg 72/2, 9744 AP Groningen The Netherlands	**Crucial Supplier**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 619995**
Date:	**2021-04-19**
Issued To:	**OrbusNeich Medical B.V.** **Drs. W.van Royenstraat 5** **3871 AN Hoevelaken** **The Netherlands**

Subcontractor:	**Service(s) supplied**
Patheon, Inc. 201 College Rd E Princeton NJ 08540 USA	**Crucial Supplier**
Quality First International OÜ Laki 30 12915 Tallinn Estonia	**EU Representative**
Ssens B.V. Pantheon 1 7521 PR Enschede The Netherlands	**Manufacture**
Sterigenics Belgium (Petit-Rechain) SA Zoning Inustriel de Petit-Rechain Avenue Andrew Ernst 21 Verviers B-4800 Belgium	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 619995**
Date:	**2021-04-19**
Issued To:	**OrbusNeich Medical B.V.** **Drs. W.van Royenstraat 5** **3871 AN Hoevelaken** **The Netherlands**

Subcontractor:	**Service(s) supplied**
SurModics, Inc 9924 W. 74th Street Eden Prairie Minnesota 55344-3523 USA	**Crucial Supplier**
Synergy Health AST, Venlo Faunalaan 38 5928 RZ Venlo The Netherlands	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 619995**
Date: **2021-04-19**
Issued To: **OrbusNeich Medical B.V.**
Drs. W.van Royenstraat 5
3871 AN Hoevelaken
The Netherlands

Date	Reference Number	Action
03 February 2015	8224626	First issue.
24 January 2016	8443505	Add product names on page 2.
12 May 2016	8450798	Add Scoreflex NC to listed product families.
22 June 2016	8558739	Add Sapphire II PRO PTA Balloon Dilatation Catheter to listed product families.
22 July 2016	8481876	Transfer scope of "drug-eluting coronary stents" from another notified body. Alignment of expiration date with transferred certificate. Add COMBO stent and COMBO Plus stent to listed product families. Add significant subcontractors and crucial suppliers associated with transfer of COMBO product: OrbusNeich Medical Inc. (USA), MeKo, BioInvent International AB, Patheon Inc., Ssens B.V., Synergy Health Ede B.V., SurModics, Inc., Fujian Kerui.
16 December 2016	8604280	Add Sapphire Coronary Dilatation Catheter to listed product families; transfer from another notified body.
15 February 2017	8661882	Transfer scope of "coronary stents" from another Notified Body. Add Azule CoCr Alloy Coronary Stent Delivery System to listed product families.
28 April 2017	8726875	Add Chunghwa Chemical Synthesis & Biotech Co., Ltd as Crucial Supplier.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 619995**
Date: **2021-04-19**
Issued To: **OrbusNeich Medical B.V.**
Drs. W.van Royenstraat 5
3871 AN Hoevelaken
The Netherlands

Date	Reference Number	Action
19 May 2017	8604338	Add ScoreFlex Coronary Dilatation Catheter, Sapphire NC Coronary Dilatation Catheter, Sapphire II NC Coronary Dilatation Catheter, and Sapphire II (RX) Coronary Dilatation Catheter to listed product families; transfer from another notified body.
5 March 2018	8730349	Addition of Teleport Microcatheter to listed product families.
18 April 2018	8883580	Certificate Renewal. Remove supplier BioInvent International AB. Correction to name of Synergy Health AST, Venlo.
08 March 2019	8250492	Traceable to NB 0086.
06 September 2019	9784371	Change of EU Representative Address. Administrative change to product table.
26 March 2020	3151777	Update device table to include Sapphire NC 24 and Sapphire 3 Coronary Dilatation Catheters.
07 July 2020	3223768	Addition of crucial suppliers Patheon Biologics BV (Groningen, The Netherlands) and Goodwin Biotechnology, Inc (Florida, USA). Removal of subcontractor OrbusNeich Medical, Inc (Florida, USA).
Current	3394028	Update to products table in supplementary information section to remove Sapphire II PRO PTA Balloon Dilatation Catheter. Correction to EU Representative address.

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 620000**

Issued To: **OrbusNeich Medical B.V.**
Drs. W.van Royenstraat 5
3871 AN Hoevelaken
The Netherlands

In respect of:

Sapphire II PRO Coronary Dilatation Catheter

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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: **2015-02-03** Date: **2020-01-10** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 620000

Issued To:

OrbusNeich Medical B.V.
Drs. W.van Royenstraat 5
3871 AN Hoevelaken
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Catalogue Number	Device Name	Diameter x Length (mm)	Intended purpose per IFU	Classification
210-053-5U	Sapphire II PRO Coronary Dilatation Catheter	1.0 x 5	The Sapphire II PRO is indicated for balloon dilatation of a stenotic portion of a coronary artery in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.	Class III
210-083-5U		1.0 x 8		Class III
210-103-5U		1.0 x 10		Class III
210-153-5U		1.0 x 15		Class III
212-053-5U		1.25 x 5		Class III
212-083-5U		1.25 x 8		Class III
212-103-5U		1.25 x 10		Class III
212-153-5U		1.25 x 15		Class III
215-103-5U		1.5 x 10		Class III
215-123-5U		1.5 x 12		Class III
215-153-5U		1.5 x 15		Class III
215-203-5U		1.5 x 20		Class III
217-103-5U		1.75 x 10		Class III
217-153-5U		1.75 x 15		Class III
217-203-5U		1.75 x 20		Class III
220-103-5U		2.0 x 10		Class III
220-123-5U		2.0 x 12		Class III

First Issued: **2015-02-03** Date: **2020-01-10** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 620000

Issued To:

OrbusNeich Medical B.V.
Drs. W.van Royenstraat 5
3871 AN Hoevelaken
The Netherlands

Catalogue Number	Device Name	Diameter x Length (mm)	Intended purpose per IFU	Classification
220-153-5U	Sapphire II PRO Coronary Dilatation Catheter	2.0 x 15	The Sapphire II PRO is indicated for balloon dilatation of a stenotic portion of a coronary artery in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.	Class III
220-203-5U		2.0 x 20		Class III
222-103-5U		2.25 x 10		Class III
222-153-5U		2.25 x 15		Class III
222-203-5U		2.25 x 20		Class III
225-103-5U		2.5 x 10		Class III
225-123-5U		2.5 x 12		Class III
225-153-5U		2.5 x 15		Class III
225-203-5U		2.5 x 20		Class III
225-303-5U		2.5 x 30		Class III
227-103-5U		2.75 x 10		Class III
227-153-5U		2.75 x 15		Class III
227-203-5U		2.75 x 20		Class III
230-103-5U		3.0 x 10		Class III
230-123-5U		3.0 x 12		Class III
230-153-5U		3.0 x 15		Class III

First Issued: **2015-02-03** Date: **2020-01-10** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 620000

Issued To:

OrbusNeich Medical B.V.
Drs. W.van Royenstraat 5
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Catalogue Number	Device Name	Diameter x Length (mm)	Intended purpose per IFU	Classification
230-203-5U	Sapphire II PRO Coronary Dilatation Catheter	3.0 x 20	The Sapphire II PRO is indicated for balloon dilatation of a stenotic portion of a coronary artery in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.	Class III
230-303-5U		3.0 x 30		Class III
232-103-5U		3.25 x 10		Class III
232-153-5U		3.25 x 15		Class III
232-203-5U		3.25 x 20		Class III
235-103-5U		3.5 x 10		Class III
235-153-5U		3.5 x 15		Class III
235-203-5U		3.5 x 20		Class III
235-303-5U		3.5 x 30		Class III
240-103-5U		4.0 x 10		Class III
240-153-5U		4.0 x 15		Class III
240-203-5U		4.0 x 20		Class III

First Issued: **2015-02-03** Date: **2020-01-10** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 620000

Issued To:

OrbusNeich Medical B.V.
Drs. W.van Royenstraat 5
3871 AN Hoevelaken
The Netherlands

Certificate History

Date	Reference Number	Action
03 February 2015	10151442	First issue.
31 January 2017	10165754	Change affecting DuPont Tyvek 1073B packaging material – all product codes are affected.
24 January 2019	8996702 9646761	Introduction of Streamline Machine System. Addition of alternative (jMedtech) hydrophilic coating.
08 March 2019	8250492	Traceable to NB 0086.
Current	9768250	Certificate Renewal. Administrative update to product table.

First Issued: **2015-02-03** Date: **2020-01-10** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 646780**

Issued To: **OrbusNeich Medical B.V.**
Drs. W.van Royenstraat 5
3871 AN Hoevelaken
The Netherlands

In respect of:

Scoreflex NC Coronary Dilatation Catheter

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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: **2016-05-12** Date: **2020-12-18** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 646780

Issued To:

OrbusNeich Medical B.V.
Drs. W.van Royenstraat 5
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The Netherlands

Scoreflex NC Company Dilation Catheter

Catalog Number	Device Name	Model, type	Intended purpose per IFU	Classification
617-104-1	Scoreflex NC Coronary Dilatation Catheter	1.75x10 mm	Scoreflex NC Coronary Dilatation Catheter is intended for balloon dilatation of a stenotic portion of a coronary artery in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.	Class III
617-154-1		1.75x15 mm		Class III
617-204-1		1.75x20 mm		Class III
620-104-1		2.0x10 mm		Class III
620-154-1		2.0x15 mm		Class III
620-204-1		2.0x20 mm		Class III
622-104-1		2.25x10 mm		Class III
622-154-1		2.25x15 mm		Class III
622-204-1		2.25x20 mm		Class III
625-104-1		2.5x10 mm		Class III
625-154-1		2.5x15 mm		Class III
625-204-1		2.5x20 mm		Class III
627-104-1		2.75x10 mm		Class III
627-154-1		2.75x15 mm		Class III
627-204-1		2.75x20 mm		Class III

First Issued: **2016-05-12** Date: **2020-12-18** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 646780

Issued To:

OrbusNeich Medical B.V.
Drs. W.van Royenstraat 5
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Catalog Number	Device Name	Model, type	Intended purpose per IFU	Classification
630-104-1	Scoreflex NC Coronary Dilatation Catheter	3.0x10 mm	Scoreflex NC Coronary Dilatation Catheter is intended for balloon dilatation of a stenotic portion of a coronary artery in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.	Class III
630-154-1		3.0x15 mm		Class III
630-204-1		3.0x20 mm		Class III
635-104-1		3.5x10 mm		Class III
635-154-1		3.5x15 mm		Class III
635-204-1		3.5x20 mm		Class III
640-104-1		4.0x10 mm		Class III
640-154-1		4.0x15 mm		Class III
640-204-1		4.0x20 mm		Class III

First Issued: **2016-05-12** Date: **2020-12-18** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 646780

Issued To:

OrbusNeich Medical B.V.
Drs. W.van Royenstraat 5
3871 AN Hoevelaken
The Netherlands

Certificate History

Date	Reference Number	Action
12 May 2016	10160141	First issue.
31 January 2017	10165754	Change affecting DuPont Tyvek 1073B packaging material – all product codes are affected.
08 March 2019	8250492	Traceable to NB 0086.
Current	3278456	Certificate renewal. Administrative change to product table.

First Issued: **2016-05-12** Date: **2020-12-18** Expiry Date: **2024-05-26**

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

OrbusNeich Medical B.V.
Drs. W.van Royenstraat 5
3871 AN Hoevelaken
The Netherlands

Holds Certificate Number: **MD 649583**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacture and distribution of sterile coronary stents, delivery systems, dilatation catheters and guiding catheters.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-06-01
Latest Revision Date: 2021-06-04

Effective Date: 2021-06-04
Expiry Date: 2023-06-07

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