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:

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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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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	---

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List of Significant Subcontractors

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

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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**
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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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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.