

DC-0034 Rev 01

DCN: 200044
EFF. DATE: 04/20/20
Page 1 of 4

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 Li*
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