

According to EC Medical Device Directive 93/42/EEC

Manufacturer: SIS MEDICAL AG
Hungerbühlstrasse 12a, 8500 Frauenfeld, Switzerland
SRN: CH-MF-000015821

EU Authorized Representative SIS MEDICAL GmbH
Florianweg 4, 72124 Pliezhausen, Germany
SRN: DE-AR-00006472

Product Name: **OPN NC**

Product Category: PTCA Dilatation Catheter

Product Classification: Class III, based on 93/42/EEC Annex IX, Rule 6

Conformity Assessment: 93/42/EEC, Annex Annex II.4

Product Codes UMDNS: 17-521 GMDN: 47732
EMDN: C010401020101

We, SIS MEDICAL AG together with our EU Authorized Representative, hereby declare under our sole responsibility that the above mentioned product as listed has been designed and manufactured in conformity to the provisions of the European Directive 93/42/EEC as amended.


Notified Body new address: TÜV NORD CERT GmbH
Am TÜV 1
45307 Essen, Germany

former address: TÜV NORD CERT GmbH
Langemarckstrasse 20
45141 Essen, Germany

Notified Body ID CE 0044

The product is supported by the following certificates:

	Certificate No.	Expiry Date
Full QA System Certificate in accordance with 93/42/EEC Annex II excluding (4)	44 232 200542	2024-05-26
EC Design Examination Certificate in accordance with 93/42/EEC Annex II.4	44 231 20054201-002	2024-05-26


Erhard J. Hüsler,
Head QA/RA, SIS MEDICAL AG


Date

Dr. Sergej Kammerzell, PRRC - 04.03.2022

Date

EU Authorized Representative
SIS MEDICAL GmbH

Technical Specifications

Catheter Usable Length (cm)	140
Balloon Diameter (mm)	1.5 / 2.0 / 2.5 / 3.0 / 3.5 / 4.0 / 4.5
Balloon Length (mm)	10 / 15 / 20
Construction Type	RX

Product Family List

OPN NC

REF Numbers			
Balloon Diameter Ø [mm]	Balloon Length [mm]		
	10	15	20
1.5	150-010-004	150-015-004	150-020-004
2.0	200-010-004	200-015-004	200-020-004
2.5	250-010-004	250-015-004	250-020-004
3.0	300-010-004	300-015-004	300-020-004
3.5	350-010-004	350-015-004	350-020-004
4.0	400-010-004	400-015-004	400-020-004
4.5	450-010-004	450-015-004	450-020-004