

**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