

Confirmation Letter: Extension of the MDR Transitional Period

Frauenfeld, May 21, 2024

TO WHOM IT MAY CONCERN

SIS Medical's PTCA catheters **OPN NC** are CE marked under MDD 93/42/EEC. The validity period of the current

EC Design Examination Certificate (No. 44 231 20054201-002 Ed. 3)

is stated as March 16, 2021 to May 26, 2024. The Notified Bodies are not authorized to change or update any CE certificates issued under MDD 93/42/EEC.

As proposed from the European Commission in March 2023 and published in the Official Journal of the European Union ([Regulation \(EU\) 2023/607](#)), the MDR transitional period was extended, which **also applies to OPN NC**.

Please note **SIS Medical's current status** in the transition from MDD to MDR certification. We have already:

- passed our Audit from our Notified Body acc. to ISO 13485:2021 and QMS requirements under MDR (EU) 2017/745 in Nov. 2023;
- applied for CE certification under MDR (EU) 2017/745 for OPN NC and submitted our documentation in January 2023. We have received feedback from the Notified Body, and the registration process is ongoing.

The **relevant passages from the Regulation (EU) 2023/607**, which apply to OPN NC PTCA catheters, are shown below.

"Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 that were still valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until the date set out in paragraph 3a of this Article applicable for the relevant risk class of the devices"

(Regulation (EU) 2023/607, Art. 1 (1) (a)).

Paragraph 3a specifies the validity period of certificates for class III medical devices, to which the PTCA catheters belong, as follows:

"Devices which have a certificate that was issued in accordance with ... Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until the following dates:

(a)

31 December 2027, for all class III devices ..."

(Regulation (EU) 2023/607, Art. 1 (1) (b), paragraph 3a)

Paragraph 3c defines the **conditions for placement on the market**, which are **all met**:

- (a) *those devices continue to comply with ... Directive 93/42/EEC, as applicable;*
- (b) *there are no significant changes in the design and intended purpose;*
- (c) *the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;*
- (d) *no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);*
- (e) *"no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the*

notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII".

(Regulation (EU) 2023/607, Art. 1 (1) (b), paragraph 3c, point e)

Please note that point e (period for application for registration under MDR (EU) 2017/745) is fulfilled because the registration under MDR (EU) 2017/745 is already ongoing.

Paragraph 3f defines the conditions on which the devices may be **made available on the market**:

"Devices lawfully placed on the market pursuant to Directives ... 93/42/EEC prior to 26 May 2021, and devices lawfully placed on the market from 26 May 2021 pursuant to paragraphs 3, 3a, 3b and 3f of this Article, may continue to be made available on the market or put into service".

(Regulation (EU) 2023/607, Art. 1 (1) (b), paragraph 3f, point c)

Conclusion

SIS Medical's PTCA catheters **OPN NC** fulfil the conditions for the **extension of the MDR transitional period**. With continuous conformance to regulation, this extension period remains valid until 31 December 2027.

Confirmation

Due to our conformance with all applicable requirements of the Regulation (EU) 2023/607 we confirm that we fulfil the conditions for the extension of the MDR transitional period and that we are legally authorized to supply you without interruption with our PTCA catheters OPN NC beyond 26. May 2024 under MDD 93/42/EEC.

This is in extension of the Declaration of Conformity:

- FM001176-015 EC Declaration of Conformity OPN NC

With continuous conformance to regulation this authorization remains valid until 31. December 2027. However, registration under MDR (EU) 2017/745 is ongoing.

In addition, our Notified Body TÜV Nord Cert GmbH has issued an Application Confirmation Letter, confirming that SIS Medical has lodged a request for conformity assessment of the OPN NC product family.

Sincerely



Dr. Sabine Mangold
Regulatory & Clinical Affairs Manager

Attachments:

- Current EC Design Examination Certificate (No. 44 231 20054201-002 Ed. 3)
- Current EC Full Quality Assurance System Certificate (No. 44 232 200 542 Ed. 2)
- Current MDD Declaration of Conformity of OPN NC (FM001176-015 EC Declaration of Conformity).

EG-Auslegungsprüfbescheinigung *EC-design examination certificate*

gem. 93/42/EWG Anhang II,4 / acc. 93/42/EEC Annex II,4

Hiermit wird bescheinigt, dass die Benannte Stelle eine EG Auslegungsprüfung des Design-Dossiers des nachfolgenden Produktes entsprechend Anhang II (4) MDD durchgeführt hat und dass die Auslegung des nachfolgend genannten Produktes den Anforderungen der Richtlinie 93/42/EWG über Medizinprodukte entspricht.

We hereby certify, that the Notified Body has performed an examination of the design dossier relating to the device in accordance with MDD Annex II (4) and found that the design of the device conforms to the requirements of MDD.

SIS Medical AG

**Hungerbühlstrasse 12a
8500 Frauenfeld
Schweiz**

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

**Katheter, Angioplastie, Ballondilatation, koronare Perfusion
*Catheters, Angioplasty, Balloon Dilatation, Coronary Perfusing***

Reg.-Nr. / Reg.-No. 44 231 20054201-002
Bericht Nr. / Report No. 3528 1378
3528 1379

Gültigkeit / Validity
von / from 2021-03-16
bis / until 2024-05-26
Edition 3

M. H. 18

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-03-16

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / ANNEX

Anlage 1, Blatt 1 von 1
Annex 1, page 1 of 1

Reg.-Nr. / Reg. No. 44 231 20054201-002

Produkte der Klasse III
Products of class III

Typ
Type

UMDNS

Katheter, Angioplastie,
Ballondilatation, koronare Perfusion
*Catheters, Angioplasty, Balloon
Dilatation, Coronary Perfusing*

OPN NC
150-010-004, 150-015-004, 150-020-004,
200-010-004, 200-015-004, 200-020-004,
250-010-004, 250-015-004, 250-020-004,
300-010-004, 300-015-004, 300-020-004,
350-010-004, 350-015-004, 350-020-004,
400-010-004, 400-015-004, 400-020-004,
450-010-004, 450-015-004, 450-020-004

17-521

Bericht Nr. / Report No. 3528 1378
3528 1379



Gültigkeit / Validity
von / from 2021-03-16
Edition 3

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-03-16

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044

EG-Zertifikat / EC-Certificate

gem. 93/42/EWG Anhang II ohne (4) / acc. 93/42/EEC Annex II without (4)

Hiermit wird bescheinigt, dass die Firma / This certifies, that the company

SIS Medical AG

Hungerbühlstrasse 12a
8500 Frauenfeld
Schweiz

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

**Katheter, Angioplastie, Ballondilatation, koronare Perfusion,
Katheter Embolektomie**

**Catheters, Angioplasty, Balloon Dilatation, Coronary
Perfusing, Catheters Embolectomy**

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennnummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / Reg.-No. 44 232 200542
Bericht Nr. / Report No. 3527 8445

Gültigkeit / Validity
von / from 2021-03-08
bis / until 2024-05-26
Edition 2



Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-03-08

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / ANNEX

Anlage 1, Blatt 1 von 1
Annex 1, page 1 of 1

Reg.-Nr. / Reg. No. 44 232 200542

Produkte der Klasse III <i>Products of class III</i>	Typ <i>Type</i>	UMDNS
Katheter, Angioplastie, Ballondilatation, koronare Perfusion <i>Catheters, Angioplasty, Balloon Dilatation, Coronary Perfusing</i>	NIC Nano hydro NIC 1.1 hydro EasyT OPN NC BEO NC	17-521
Katheter, Embolektomie <i>Catheters, Embolectomy</i>	Xtrac EC Aspiration Catheter	10-714

Anmerkung: Für das Inverkehrbringen der in diesem Zertifikat genannten Klasse III Produkte wird eine gültige EG Auslegungsprüfbescheinigung gemäß MDD Anhang II (4) gefordert.

Note: For the placing on the market of Class III devices covered by this certificate, a valid EC design-examination certificate according to MDD Annex II (4) is required.

Bericht Nr. / Report No. 3527 8445

Gültigkeit / Validity
von / from 2021-05-14
Edition 3



Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-05-14

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

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 EUMEDIQ GmbH
Mörfelder Landstraße 6-8, 60598 Frankfurt am Main, Germany
DE-AR-000007809

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 TÜV NORD CERT GmbH
Am TÜV 1
45307 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

30 Nov. 2023
Date

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