Certificate

EC Design Examination
Annex II.4 of the Directive on Medical Devices

ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that a design examination has been carried out on the device(s) listed in annex I to this certificate following the requirements of annex II.4 of the Directive 93/42/EEC.

This certificate is issued on behalf of:

Manufacturer

SIS Medical AG
Hungerbüelstrasse 12a, 8500 Frauenfeld, Switzerland

ECM certifies that the design of the device(s) listed in annex I to this certificate conforms with the requirements of annex II.4 of the Directive 93/42/EEC on medical devices.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

Any substantial changes of the examined product design or changes in the manufacturing process which might affect conformity to the essential requirements of the Directive 93/42/EEC or with the conditions prescribed for use of the product have to be notified to ECM and are subject to a separate approval.
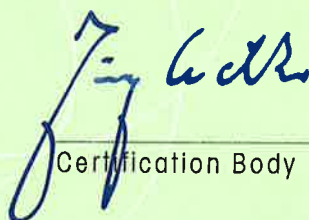
Report Number	Registered under	Valid until
256-112072	Z/18/04281E	July 15th, 2023

Valid as of: July 16th, 2018

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Certification Body

ZLG-BS-240.10.12

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten

ecm

Zertifizierungsgesellschaft für
Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code[1]
single use device	Catheters, Vascular, Angioplasty, Balloon, Coronary Perfusion	17-521

hydrophilic coated balloons:
-- NIC Nano hydro
085-006-134, 085-010-134,
085-015-134
-- NIC 1.1 hydro
110-006-134, 110-010-134,
110-015-134, 110-020-134
-- Easy T
150-006-134, 150-010-134,
150-015-134, 150-020-134,
200-006-134, 200-010-134,
200-015-134, 200-020-134,
200-025-134, 200-030-134,
250-006-134, 250-010-134,
250-015-134, 250-020-134,
250-025-134, 250-030-134

hydrophobic coated balloons:
-- Easy T
300-006-134, 300-010-134,
300-015-134, 300-020-134,
300-025-134, 300-030-134,
350-006-134, 350-010-134,
350-015-134, 350-020-134,
350-025-134, 350-030-134,
400-006-134, 400-010-134,
400-015-134, 400-020-134,
400-025-134, 400-030-134,
450-006-134, 450-010-134,
450-015-134, 450-020-134,
450-025-134, 450-030-134

Special terms of validity:

[1] UMDNS Code ist optional