Diameters and lengths - straight stents

GSS™ TD / GSS™ TF / GSS™ BD / DUMON® BB

Determine the desired stent length (stenosis length + 10 mm)
and diameter and select from the available stents.

Custom-made stents are possible.
Contact us!

Length (mm) ► / Outer Diameter (mm) ▼	20	30	40	50	60	70	80	90	100	110
5	025301S20 **(BB)**	025301S30 **(BB)**	025301S40 **(BB)**	025301S50 **(BB)**						
6	026201S20 **(BB)**	026201S30 **(BB)**	026201S40 **(BB)**	026201S50 **(BB)**						
7	026501S20 **(BB)**	026501S30 **(BB)**	026501S40 **(BB)**	026501S50 **(BB)**						
8	026701S20 **(BB)**	026701S30 **(BB)**	026701S40 **(BB)**	026701S50 **(BB)**						
10	01**BD**1020	01**BD**1030	01**BD**1040	01**BD**1050	01**BD**1060	01**BD**1070				
11	01**BD**1120 01**TD**1120	01**BD**1130 01**TD**1130	01**BD**1140 01**TD**1140	01**BD**1150 01**TD**1150	01**BD**1160 01**TD**1160	01**BD**1170 01**TD**1170	01**TD**1180			
12	01**BD**1220 01**TD**1220	01**BD**1230 01**TD**1230 01**TF**1230	01**BD**1240 01**TD**1240 01**TF**1240	01**BD**1250 01**TD**1250 01**TF**1250	01**BD**1260 01**TD**1260 01**TF**1260	01**BD**1270 01**TD**1270 01**TF**1270	01**BD**1280 01**TD**1280 01**TF**1280			
13		01**TD**1330 01**TF**1330	01**TD**1340 01**TF**1340	01**TD**1350 01**TF**1350	01**TD**1360 01**TF**1360	01**TD**1370 01**TF**1370	01**TD**1380			
14		01**TD**1430 01**TF**1430	01**TD**1440 01**TF**1440	01**TD**1450 01**TF**1450	01**TD**1460 01**TF**1460	01**TD**1470 01**TF**1470	01**TD**1480			
15		01**TD**1530 01**TF**1530	01**TD**1540 01**TF**1540	01**TD**1550 01**TF**1550	01**TD**1560 01**TF**1560	01**TD**1570 01**TF**1570	01**TD**1580 01**TF**1580	01**TD**1590 01**TF**1590	01**TD**15100 01**TF**15100	01**TD**15110 01**TF**15110
16		01**TD**1630	01**TD**1640 01**TF**1640	01**TD**1650 01**TF**1650	01**TD**1660 01**TF**1660	01**TD**1670 01**TF**1670	01**TD**1680 01**TF**1680	01**TD**1690 01**TF**1690	01**TD**16100 01**TF**16100	01**TD**16110
18			01**TD**1840 01**TF**1840	01**TD**1850 01**TF**1850	01**TF**1860	01**TF**1870	01**TF**1880	01**TF**1890	01**TF**18100	01**TF**18110
20			01**TF**2040	01**TF**2050	01**TF**2060	01**TF**2070	01**TF**2080	01**TF**2090	01**TF**20100	01**TF**20110

GSS™ TD

GSS™ TF

GSS™ BD

DUMON® BB

EC Declaration of Conformity

Manufacturer	Novatech SA Z.I. Athélia III - 1058, Voie Antiope 13705 La Ciotat CEDEX, France
Medical Device	**NOVATECH® GSS™** *See REF-s below*
Device Classification	Class IIb Rule 8
MD Code / GMDN Code	0203 / 46977
Notified Body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany Identification Number: 0297
CE Marking First Applied	6 December 2010

Novatech SA declares on its own responsibility that the above mentioned product meets the provisions of Council Directive 93/42/EEC for Medical Devices.

The conformity has been assessed according to Annex II excluding Section 4 of MDD 93/42/EEC [Certificate No. 170773598] and EN ISO 13485 [Certificate No. 170763138].

We herewith declare that the manufacturer is exclusively responsible for issuing the declaration of conformity.

This declaration of conformity is valid until the issuing of a revised version after change of a product or until 2024-05-26. whichever occurs first.

Berlin, 2021-01-07

Heiko Jacobs / Director QM

REF	Product Name	Description
01TD1120	NOVATECH® GSS™ TD	TD 11 L 20
01TD1130	NOVATECH® GSS™ TD	TD 11 L 30
01TD1140	NOVATECH® GSS™ TD	TD 11 L 40
01TD1150	NOVATECH® GSS™ TD	TD 11 L 50
01TD1160	NOVATECH® GSS™ TD	TD 11 L 60
01TD1170	NOVATECH® GSS™ TD	TD 11 L 70
01TD1180	NOVATECH® GSS™ TD	TD 11 L 80
01TD1220	NOVATECH® GSS™ TD	TD 12 L 20
01TD1230	NOVATECH® GSS™ TD	TD 12 L 30
01TD1240	NOVATECH® GSS™ TD	TD 12 L 40
01TD1250	NOVATECH® GSS™ TD	TD 12 L 50
01TD1260	NOVATECH® GSS™ TD	TD 12 L 60
01TD1270	NOVATECH® GSS™ TD	TD 12 L 70
01TD1280	NOVATECH® GSS™ TD	TD 12 L 80
01TD1330	NOVATECH® GSS™ TD	TD 13 L 30
01TD1340	NOVATECH® GSS™ TD	TD 13 L 40
01TD1350	NOVATECH® GSS™ TD	TD 13 L 50
01TD1360	NOVATECH® GSS™ TD	TD 13 L 60
01TD1370	NOVATECH® GSS™ TD	TD 13 L 70
01TD1380	NOVATECH® GSS™ TD	TD 13 L 80
01TD1430	NOVATECH® GSS™ TD	TD 14 L 30
01TD1440	NOVATECH® GSS™ TD	TD 14 L 40
01TD1450	NOVATECH® GSS™ TD	TD 14 L 50

01TD1460	NOVATECH® GSS™ TD	TD 14 L 60
01TD1470	NOVATECH® GSS™ TD	TD 14 L 70
01TD1480	NOVATECH® GSS™ TD	TD 14 L 80
01TD1530	NOVATECH® GSS™ TD	TD 15 L 30
01TD1540	NOVATECH® GSS™ TD	TD 15 L 40
01TD1550	NOVATECH® GSS™ TD	TD 15 L 50
01TD1560	NOVATECH® GSS™ TD	TD 15 L 60
01TD1570	NOVATECH® GSS™ TD	TD 15 L 70
01TD1580	NOVATECH® GSS™ TD	TD 15 L 80
01TD1590	NOVATECH® GSS™ TD	TD 15 L 90
01TD15100	NOVATECH® GSS™ TD	TD 15 L 100
01TD15110	NOVATECH® GSS™ TD	TD 15 L 110
01TD1630	NOVATECH® GSS™ TD	TD 16 L 30
01TD1640	NOVATECH® GSS™ TD	TD 16 L 40
01TD1650	NOVATECH® GSS™ TD	TD 16 L 50
01TD1660	NOVATECH® GSS™ TD	TD 16 L 60
01TD1670	NOVATECH® GSS™ TD	TD 16 L 70
01TD1680	NOVATECH® GSS™ TD	TD 16 L 80
01TD1690	NOVATECH® GSS™ TD	TD 16 L 90
01TD16100	NOVATECH® GSS™ TD	TD 16 L 100
01TD16110	NOVATECH® GSS™ TD	TD 16 L 110
01TD1840	NOVATECH® GSS™ TD	TD 18 L 40
01TD1850	NOVATECH® GSS™ TD	TD 18 L 50
01TF1230	NOVATECH® GSS™ TF	TF 12 L 30

01TF1240	NOVATECH® GSS™ TF	TF 12 L 40
01TF1250	NOVATECH® GSS™ TF	TF 12 L 50
01TF1260	NOVATECH® GSS™ TF	TF 12 L 60
01TF1270	NOVATECH® GSS™ TF	TF 12 L 70
01TF1280	NOVATECH® GSS™ TF	TF 12 L 80
01TF1330	NOVATECH® GSS™ TF	TF 13 L 30
01TF1340	NOVATECH® GSS™ TF	TF 13 L 40
01TF1350	NOVATECH® GSS™ TF	TF 13 L 50
01TF1360	NOVATECH® GSS™ TF	TF 13 L 60
01TF1370	NOVATECH® GSS™ TF	TF 13 L 70
01TF1430	NOVATECH® GSS™ TF	TF 14 L 30
01TF1440	NOVATECH® GSS™ TF	TF 14 L 40
01TF1450	NOVATECH® GSS™ TF	TF 14 L 50
01TF1460	NOVATECH® GSS™ TF	TF 14 L 60
01TF1470	NOVATECH® GSS™ TF	TF 14 L 70
01TF1530	NOVATECH® GSS™ TF	TF 15 L 30
01TF1540	NOVATECH® GSS™ TF	TF 15 L 40
01TF1550	NOVATECH® GSS™ TF	TF 15 L 50
01TF1560	NOVATECH® GSS™ TF	TF 15 L 60
01TF1570	NOVATECH® GSS™ TF	TF 15 L 70
01TF1580	NOVATECH® GSS™ TF	TF 15 L 80
01TF1590	NOVATECH® GSS™ TF	TF 15 L 90
01TF15100	NOVATECH® GSS™ TF	TF 15 L 100

01TF15110	NOVATECH® GSS™ TF	TF 15 L 110
01TF1640	NOVATECH® GSS™ TF	TF 16 L 40
01TF1650	NOVATECH® GSS™ TF	TF 16 L 50
01TF1660	NOVATECH® GSS™ TF	TF 16 L 60
01TF1670	NOVATECH® GSS™ TF	TF 16 L 70
01TF1680	NOVATECH® GSS™ TF	TF 16 L 80
01TF1690	NOVATECH® GSS™ TF	TF 16 L 90
01TF16100	NOVATECH® GSS™ TF	TF 16 L 100
01TF1840	NOVATECH® GSS™ TF	TF 18 L 40
01TF1850	NOVATECH® GSS™ TF	TF 18 L 50
01TF1860	NOVATECH® GSS™ TF	TF 18 L 60
01TF1870	NOVATECH® GSS™ TF	TF 18 L 70
01TF1880	NOVATECH® GSS™ TF	TF 18 L 80
01TF1890	NOVATECH® GSS™ TF	TF 18 L 90
01TF18100	NOVATECH® GSS™ TF	TF 18 L 100
01TF18110	NOVATECH® GSS™ TF	TF 18 L 110
01TF2040	NOVATECH® GSS™ TF	TF 20 L 40
01TF2050	NOVATECH® GSS™ TF	TF 20 L 50
01TF2060	NOVATECH® GSS™ TF	TF 20 L 60
01TF2070	NOVATECH® GSS™ TF	TF 20 L 70
01TF2080	NOVATECH® GSS™ TF	TF 20 L 80
01TF2090	NOVATECH® GSS™ TF	TF 20 L 90
01TF20100	NOVATECH® GSS™ TF	TF 20 L 100

01TF20110	NOVATECH® GSS™ TF	TF 20 L 110
01ST121012	NOVATECH® GSS™ ST	ST 12-10-12 L 15-20-15
01ST141214	NOVATECH® GSS™ ST	ST 14-12-14 L 15-20-15
01ST151315	NOVATECH® GSS™ ST	ST 15-13-15 L 15-20-15
01ST161416	NOVATECH® GSS™ ST	ST 16-14-16 L 15-20-15
01ST181618	NOVATECH® GSS™ ST	ST 18-16-18 L 15-20-15
01DST141214	NOVATECH® GSS™ ST	ST 14-12-14 L 7.5-20-7.5
01DST161416	NOVATECH® GSS™ ST	ST 16-14-16 L 7.5-20-7.5
01DST181618	NOVATECH® GSS™ ST	ST 18-16-18 L 7.5-20-7.5
01BD1020	NOVATECH® GSS™ BD	BD 10 L 20
01BD1030	NOVATECH® GSS™ BD	BD 10 L 30
01BD1040	NOVATECH® GSS™ BD	BD 10 L 40
01BD1050	NOVATECH® GSS™ BD	BD 10 L 50
01BD1060	NOVATECH® GSS™ BD	BD 10 L 60
01BD1070	NOVATECH® GSS™ BD	BD 10 L 70
01BD1120	NOVATECH® GSS™ BD	BD 11 L 20
01BD1130	NOVATECH® GSS™ BD	BD 11 L 30
01BD1140	NOVATECH® GSS™ BD	BD 11 L 40
01BD1150	NOVATECH® GSS™ BD	BD 11 L 50
01BD1160	NOVATECH® GSS™ BD	BD 11 L 60
01BD1170	NOVATECH® GSS™ BD	BD 11 L 70
01BD1220	NOVATECH® GSS™ BD	BD 12 L 20

01BD1230	NOVATECH® GSS™ BD	BD 12 L 30
01BD1240	NOVATECH® GSS™ BD	BD 12 L 40
01BD1250	NOVATECH® GSS™ BD	BD 12 L 50
01BD1260	NOVATECH® GSS™ BD	BD 12 L 60
01BD1270	NOVATECH® GSS™ BD	BD 12 L 70
01BD1280	NOVATECH® GSS™ BD	BD 12 L 80
01Y121010	NOVATECH® GSS™ Y	Y 12-10-10 L 70-50-50
01Y141010	NOVATECH® GSS™ Y	Y 14-10-10 L 110-50-50
01Y141010V1	NOVATECH® GSS™ Y	Y 14-10-10 L 40-30-30
01Y151212	NOVATECH® GSS™ Y	Y 15-12-12 L 110-50-50
01Y151212V1	NOVATECH® GSS™ Y	Y 15-12-12 L 40-30-30
01Y151212V2	NOVATECH® GSS™ Y	Y 15-12-12 L 50-30-30
01Y161313	NOVATECH® GSS™ Y	Y 16-13-13 L 110-50-50
01Y161313V1	NOVATECH® GSS™ Y	Y 16-13-13 L 40-30-30
01Y161313V2	NOVATECH® GSS™ Y	Y 16-13-13 L 50-30-30
01Y181414	NOVATECH® GSS™ Y	Y 18-14-14 L 110-50-50
01OKI130910	NOVATECH® GSS™ OKI	OKI 13-09-10 L 40-17-35

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

NOVATECH SA

Z.I. Athélia III
1058, Voie Antiope
13705 La Ciotat CEDEX
France

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Interventional Pulmonology Products, Thoracic Surgery Products, Interdisciplinary Products according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	501581 MR2
Certificate unique ID	170773598
Effective date	2020-11-17
Expiry date	2024-05-26
Frankfurt am Main	2020-11-17

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 501581 MR2
Certificate unique ID: 170773598
Effective date: 2020-11-17

NOVATECH SA

Z.I. Athélia III
1058, Voie Antiope
13705 La Ciotat CEDEX
France

Device family	Device	Class
Interventional Pulmonology Products	Respiratory Stents	IIb
	Bronchial Plugs	IIb
	Endoscopes	IIa
	Protection for Endoscopes	Is
	Endobronchial Lung Marker	IIb
Thoracic Surgery Products	Sterile Talcum Powder	IIb
	Pleura Trocars	IIa
Interdisciplinary Products	Silicone Sheeting unrestricted	IIb
	Silicone Sheeting restricted	IIa
	Surgical Suction Catheters	IIa

CERTIFICATE

This is to certify that the company

NOVATECH SA

Z.I. Athélia III
1058, Voie Antiope
13705 La Ciotat CEDEX
France

has implemented and maintains a **Quality Management System**.

Scope:
Development, production and distribution of medical devices: implants (including medical device variants, i.e. "patient matched" implants, and custom-made medical devices), single-use medical devices, instruments and accessories in the fields of interventional pulmonology and thoracic surgery including tracheal and bronchial stents / bronchial plugs / sterile talcum powder / silicone sheetings / bronchoscopes / pleura trocars / surgical suction tubes.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	501581 MP2016
Certificate unique ID	170780212
Effective date	2022-05-02
Expiry date	2023-09-16
Frankfurt am Main	2022-05-02

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

CERTIFICATE

This is to certify that the company

NOVATECH SA

Z.I. Athélia III
1058, Voie Antiope
13705 La Ciotat CEDEX
France

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:
Development, production and distribution of medical devices such as implants, instruments and accessories in the field of interventional pulmonology and thoracic surgery including tracheal and bronchial stents / bronchial plugs / sterile talcum powder / silicone sheetings / endoscopes / pleural trocars and surgical suction catheters.
-AUS (a), BRA, CND, JPN, USA (a,b,c,d,e)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	501581 MDSAP16
Certificate unique ID	170763139
Effective date	2020-09-17
Expiry date	2023-09-16
Frankfurt am Main	2020-09-17

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

Annex to certificate
Certificate registration No.: 501581 MDSAP16
Certificate unique ID: 170763139
Effective date: 2020-09-17

NOVATECH SA

Z.I. Athélia III
1058, Voie Antiope
13705 La Ciotat CEDEX
France

Audited site	DUNS No., site scope and country-specific requirements
NOVATECH SA Z.I. Athélia III 1058, Voie Antiope 13705 La Ciotat CEDEX France	Development, production and distribution of medical devices such as implants, instruments and accessories in the field of interventional pulmonology and thoracic surgery including tracheal and bronchial stents / bronchial plugs / sterile talcum powder / silicone sheetings / endoscopes / pleural trocars and surgical suction catheters. **-AUS (a), BRA, CND, JPN, USA (a,b,c,d,e)** **DUNS No.: 777211640**

Annex to certificate
Certificate registration No.: 501581 MDSAP16
Certificate unique ID: 170763139
Effective date: 2020-09-17

NOVATECH SA

Z.I. Athélia III
1058, Voie Antiope
13705 La Ciotat CEDEX
France

Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821