

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	01BD1020	01BD1030	01BD1040	01BD1050	01BD1060	01BD1070				
11	01BD1120 01TD1120	01BD1130 01TD1130	01BD1140 01TD1140	01BD1150 01TD1150	01BD1160 01TD1160	01BD1170 01TD1170	01TD1180			
12	01BD1220 01TD1220	01BD1230 01TD1230 01TF1230	01BD1240 01TD1240 01TF1240	01BD1250 01TD1250 01TF1250	01BD1260 01TD1260 01TF1260	01BD1270 01TD1270 01TF1270	01BD1280 01TD1280 01TF1280			
13		01TD1330 01TF1330	01TD1340 01TF1340	01TD1350 01TF1350	01TD1360 01TF1360	01TD1370 01TF1370	01TD1380			
14		01TD1430 01TF1430	01TD1440 01TF1440	01TD1450 01TF1450	01TD1460 01TF1460	01TD1470 01TF1470	01TD1480			
15		01TD1530 01TF1530	01TD1540 01TF1540	01TD1550 01TF1550	01TD1560 01TF1560	01TD1570 01TF1570	01TD1580 01TF1580	01TD1590 01TF1590	01TD15100 01TF15100	01TD15110 01TF15110
16		01TD1630	01TD1640 01TF1640	01TD1650 01TF1650	01TD1660 01TF1660	01TD1670 01TF1670	01TD1680 01TF1680	01TD1690 01TF1690	01TD16100 01TF16100	01TD16110
18			01TD1840 01TF1840	01TD1850 01TF1850	01TF1860	01TF1870	01TF1880	01TF1890	01TF18100	01TF18110
20			01TF2040	01TF2050	01TF2060	01TF2070	01TF2080	01TF2090	01TF20100	01TF20110



GSS™ TD



GSS™ TF



GSS™ BD



DUMON® BB





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.



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

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



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



DQS Medizinprodukte GmbH

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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



DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.

Visit <https://www.mydqs.com/en/customers/customer-database.html> to validate this certificate.



Annex to certificate

Certificate registration No.: 501581 MDSAP16

Certificate unique ID: 170763139

Effective date: 2020-09-17

NOVATECH SA

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1058, Voie Antiope
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Audited site

NOVATECH SA
Z.I. Athélia III
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13705 La Ciotat CEDEX
France

DUNS No., site scope and country-specific requirements

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

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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