

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) ▶ | 20 | 30 | 40 | 50 | 60 | 70 | 80 | 90 | 100 | 110 |
|-----------------------|----------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------|------------------------|------------------------|
| 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

NOVATECH SA

Z.I. Athélia III
1058, Voie Antiope
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| 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 |



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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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

Sigrid Uhlemann
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Product Manager

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Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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

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

Audited site

NOVATECH SA
Z.I. Athélia III
1058, Voie Antiope
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

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 |

| | | |
|---|------------------------------|-----------------|
|  | Form (FOR) | NOV-RA-FOR-0226 |
| | EC Declaration of Conformity | Revision: 2 |

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

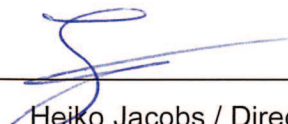
Novatech SA declares on its own responsibility that the above mentioned product meets the provisions of Council Directive 93/42/EEC for Medical Devices.

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

| | | |
|---|-------------|--------------|
| TMP #: GRP-QM-TMP-0001 | TMP Rev.: 1 | Page: 1 of 7 |
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Form (FOR)

NOV-RA-FOR-0226

EC Declaration of Conformity

Revision: 2

| 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 |



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Form (FOR)

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EC Declaration of Conformity

Revision: 2

| | | |
|-----------|-------------------|-------------|
| 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 |



Form (FOR)

NOV-RA-FOR-0226

EC Declaration of Conformity

Revision: 2

| | | |
|-----------|-------------------|-------------|
| 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 |



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Revision: 2

| | | |
|-----------|-------------------|-------------|
| 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 |



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Revision: 2

| | | |
|-------------|-------------------|--------------------------|
| 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 |

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TMP Rev.: 1

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Form (FOR)

NOV-RA-FOR-0226

EC Declaration of Conformity

Revision: 2

| | | |
|-------------|--------------------|-------------------------|
| 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 |