MOBIAS BANCA

Nr. 12101-304

18.03.2016

# CERTIFICAT
# PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **BC „Mobiasbancă – Groupe Societe Generale" S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **OXIVIT-MED SRL**, cod fiscal (IDNO) **1007600044280,** deține următoarele conturi curente la BC "Mobiasbancă-Groupe Societe Generale" S.A., Filiala. 1 Stejaur :

1. **MDL - 2224710SV23488147100; IBAN- MD09MO2224ASV23488147100**
2. **EUR - 2224710SV22227957100; IBAN- MD17MO2224ASV22227957100**
3. **USD - 2224710SV22214937100; IBAN- MD86MO2224ASV22214937100**

Certificatul este emis în baza cererii întreprinderii: Oxivit-Med SRL.

L.Ș.

Dumitru Popa
**Director filială „Stejaur"**

Executor : Mariana Guzun
Tel: 022 812 614

Digitally signed by Kojevnikov Dmitrii
Date: 2024.02.02 15:32:18 EET
Reason: MoldSign Signature
Location: Moldova

Filiala Nr. 1 „Stejaur"
Bd. Ştefan cel Mare şi Sfânt 196
MD-2004, Chişinău, Moldova
Cod MOBBMD22
Cont de corespondenţă 35213892
la Centrul de Decontări al BNM

Tel. +373 22 81 26 15
Fax. +373 22 81 26 15
www.mobiasbanca.md

BC „Mobiasbancă – Groupe Société Générale" SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat - 1002600006089
Sediul Central:
bd. Ştefan cel Mare şi Sfânt 81a
MD-2012, Chişinău, Moldova

REPUBLICA MOLDOVA

# CERTIFICAT DE ÎNREGISTRARE

**Societatea Comercială "OXIVIT-MED" S.R.L.**

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

*Numărul de identificare de stat - codul fiscal*

**1007600044280**

*Data înregistrării* **30.07.2007**

*Data eliberării* **30.07.2007**

**Bordeianu Tatiana, registrator de stat**

*Funcția, numele, prenumele persoanei care a eliberat certificatul*

*semnătura*

CAMERA ÎNREGISTRĂRII DE STAT A REPUBLICII MOLDOVA L.Ș.

MD 0067985

# AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

## EXTRAS

**din Registrul de stat al persoanelor juridice**

Nr. **531861** data **19.09.2023**

Denumirea completă: **Societatea Comercială "OXIVIT-MED" S.R.L.**
Denumirea prescurtată: **S.C. "OXIVIT-MED" S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată,**
Numărul de identificare de stat şi codul fiscal (IDNO): **1007600044280**
Data înregistrării de stat: **30.07.2007**
Sediul: **MD-2032, bd . Decebal, 82, ap.(of.) 90, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
**1. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală**
**2. Comerţul cu ridicata al parfumurilor şi produselor cosmetice**
**3. Comerţul cu amănuntul al produselor cosmetice şi de parfumerie, articolelor de toaletă**
**4. Intermedieri pentru vînzarea unui asortiment larg de mărfuri**
**5. Alte tipuri de comerţ cu amănuntul în magazine nespecializate**
**6. Alte tipuri de comerţ cu ridicata**
**7. Închirierea altor maşini şi echipamente**

Capitalul social: **5400** lei,

Administrator: **KOJEVNIKOV DMITRII, IDNP 0972305012362,**

Asociaţii:
1. KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 5400 lei, ce constituie 100%
Beneficiar efectiv:
1.1. KOJEVNIKOV DMITRII, IDNP 0972305012362

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: **19.09.2023**.

**Registrator în domeniul înregistrării de stat** **Rusu Diana**

Digitally signed by Rusu Diana
Date: 2023.09.19 11:22:47 EEST
Reason: MoldSign Signature
Location: Moldova

EB 0461498

Date cu caracter personal

c/f: 1007600044280; adresa: str. Decebal 82-90, or. Chișinău, Republica Moldova
telefon: + 373 22 808002; fax: + 373 22 808003
web: www.oxivit-med.com; e-mail:info@oxivit-med.com

# ***Lista fondatorilor companiei SRL „Oxivit-Med”***

| Nr. | Numele, Prenumele | Codul Personal |
|---|---|---|
| 1 | Kojevnikov Dmitrii | 0972305012362 |

c/f: 1007600044280; adresa: str. Decebal 82-90, or. Chișinău, Republica Moldova
telefon: + 373 22 808002; fax: + 373 22 808003
web: www.oxivit-med.com; e-mail:info@oxivit-med.com

# Date generale despre ofertant

| **S.C. OXIVIT-MED S.R.L** |
|---|
| **Administrator:** Dmitrii Kojevnikov |
| **Adresa poştală:** mun. Chișinău, str. Decebal 82-90 |
| **Tel./Fax:** 022 808 002, 022 808 003<br>**E-mail:** info@oxivit-med.com; oxivit.medical@gmail.com |
| **Cod IBAN:** MD09MO2224ASV23488147100 |
| **Banca:** „Mobiasbanca OTP Group” S.A |
| **Codul băncii:** MOBBMD22 |
| **Cod fiscal:** 1007600044280 |
| **Cod TVA:** 0306300 |

Cu respect,

Dmitrii Kojevnikov

Administrator

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

# EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

**No. G1 077608 0079 Rev. 00**

**Manufacturer:**

**Covidien llc**
15 Hampshire Street
Mansfield, MA 02048
USA

**Product Category(ies):** **Medical Instruments, Surgical Products and Hemostatic Materials:**

- **Surgical Suture Products, Pledgets and Retention Tapes**
- **Endoscopy Instruments and Accessories including Lubricant**
- **Surgical Staple, Clip Products and Accessories**
- **Manual Surgical Instruments**
- **Implantable Wound Dressing Materials**
- **Ultrasonic Surgical Devices and Accessories**
- **Suction / Irrigation Devices and Accessories**
- **Arthroscopy Implants, Instruments and Accessories**
- **Bone Wax**
- **Temporary Cardiac Pacing Lead**
- **Powered Stapling Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** 713164286

**Valid from:** 2019-09-13
**Valid until:** 2024-05-26

**Date,** 2019-09-13

Stefan Preiß
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

# EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

**No. G1 077608 0079 Rev. 00**

**Facility(ies):**

**Covidien llc**
15 Hampshire Street,
Mansfield, MA 02048, USA

./.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT


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COVIDIEN

# Declaration of Conformity

## USS-108

We hereby declare, under our sole responsibility, that the devices specified below meet the relevant provisions of the Council Directive concerning medical devices- 93/42/EEC and the Essential Principles. This is also a declaration made in accordance with the requirements of Clause 1.8 of schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the stated device.

| | |
|---|---|
| **Issued by Manufacturer:** | **Covidien llc**<br>**15 Hampshire Street**<br>**Mansfield, MA 02048, U.S.A.** |
| **Original Date/Place of Issue:** | **11/21/2001 North Haven, CT U.S.A.** |
| **Type of Devices:** | **Temporary Cardiac Pacing Lead** |
| **Device Name:** | **Flexon™ Multifilament Temporary Cardiac Pacing Lead** |
| **Product Category(ies) listed on Current MDD certificates:** | **Non-Active Implants, Temporary Cardiac Pacing Lead, Flexon™** |
| **MDD Classification/ Reorder Codes/GMDN Codes:** | **See Attached** |
| **Conformity Assessment:** | **Directive 93/42/EEC on Medical Devices (MDD), Annex II** |
| **Design Examination Certificate #:** | **G7 077608 0044 Rev 02 (expires 26-May-2024)** |
| **EC Certificate #:** | **G1 077608 0079 Rev 00 (expires 26-May-2024)** |
| **Declaration of Conformity Valid Until:** | **26-May-2024** |
| **Standards Associated:** | **See Attached** |

**Authorized Representative in EU**
Covidien Ireland Limited
IDA Business and Technology Park
Tullamore, Ireland

**Notified Body**
TUV SUD Product Service GmbH
Ridlerstrasse 65,
80339 Munich, Germany (0123)

Revision Date: January 12, 2021


REGULATORY AFFAIRS COVIDIEN NORTH HAVEN, CONNECTICUT USA

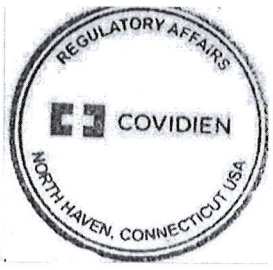
Angela Van Arsdale
Angela Van Arsdale
Sr. Manager, Regulatory Affairs

COVIDIEN

# Declaration of Conformity

## USS - 108

| Reorder Code | Description | MDD Class | MDD Rule | GMDN | Date Added to Declaration M/D/YYYY | Reorder Code Status |
|---|---|---|---|---|---|---|
| 8886258643 | Flexon™ FEP Coated Multifilament Stainless Steel Nonabsorbable Temporary Cardiac Pacing Lead | III | 8 | Pacing lead, external, transthoracic, temporary [45966] | 02/11/2011 | Current |
| 8886258643-2 | Flexon™ FEP Coated Multifilament Stainless Steel Nonabsorbable Temporary Cardiac Pacing Lead | III | 8 | Pacing lead, external, transthoracic, temporary [45966] | 03/10/2020 | Current |
| 8886258963 | Flexon™ FEP Coated Multifilament Stainless Steel Nonabsorbable Temporary Cardiac Pacing Lead | III | 8 | Pacing lead, external, transthoracic, temporary [45966] | 02/11/2011 | Current |
| 8886259143 | Flexon™ FEP Coated Multifilament Stainless Steel Nonabsorbable Temporary Cardiac Pacing Lead | III | 8 | Pacing lead, external, transthoracic, temporary [45966] | 02/11/2011 | Current |
| 8886259143-2 | Flexon™ FEP Coated Multifilament Stainless Steel Nonabsorbable Temporary Cardiac Pacing Lead | III | 8 | Pacing lead, external, transthoracic, temporary [45966] | 03/10/2020 | Current |
| 8886259243 | Flexon™ FEP Coated Multifilament Stainless Steel Nonabsorbable Temporary Cardiac Pacing Lead | III | 8 | Pacing lead, external, transthoracic, temporary [45966] | 02/11/2011 | Current |


Angela Van Arsdale
Angela Van Arsdale
Sr. Manager, Regulatory Affairs

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# Declaration of Conformity

## USS - 108

| Reorder Code | Description | MDD Class | MDD Rule | GMDN | Date Added to Declaration M/D/YYYY | Reorder Code Status |
|---|---|---|---|---|---|---|
| 8886259243-2 | Flexon™ FEP Coated Multifilament Stainless Steel Nonabsorbable Temporary Cardiac Pacing Lead | III | 8 | Pacing lead, external, transthoracic, temporary [45966] | 03/10/2020 | Current |
| 8886259363 | Flexon™ FEP Coated Multifilament Stainless Steel Nonabsorbable Temporary Cardiac Pacing Lead | III | 8 | Pacing lead, external, transthoracic, temporary [45966] | 02/11/2011 | Current |
| 8886259363-2 | Flexon™ FEP Coated Multifilament Stainless Steel Nonabsorbable Temporary Cardiac Pacing Lead | III | 8 | Pacing lead, external, transthoracic, temporary [45966] | 03/10/2020 | Current |
| 8886259763 | Flexon™ FEP Coated Multifilament Stainless Steel Nonabsorbable Temporary Cardiac Pacing Lead | III | 8 | Pacing lead, external, transthoracic, temporary [45966] | 02/11/2011 | Current |
| 8886261753 | Flexon™ FEP Coated Multifilament Stainless Steel Nonabsorbable Temporary Cardiac Pacing Lead | III | 8 | Pacing lead, external, transthoracic, temporary [45966] | 02/11/2011 | Current |
| 8886261553 | Flexon™ FEP Coated Multifilament Stainless Steel Nonabsorbable Temporary Cardiac Pacing Lead | III | 8 | Pacing lead, external, transthoracic, temporary [45966] | 02/11/2011 | Current |
| 8886262353 | Flexon™ FEP Coated Multifilament Stainless Steel Nonabsorbable Temporary Cardiac Pacing Lead | III | 8 | Pacing lead, external, transthoracic, temporary [45966] | 02/11/2011 | Current |

REGULATORY AFFAIRS COVIDIEN NORTH HAVEN, CONNECTICUT USA

Angela Van Arsdale
Angela Van Arsdale
Sr. Manager, Regulatory Affairs

COVIDIEN

# Declaration of Conformity

## USS - 108

**Model(s):** **Flexon™ Temporary Cardiac Pacing Lead**

**Parameters:**

| Reorder Code | Straight Needle | | | Suture Wire | | | Curved Needle | | |
|---|---|---|---|---|---|---|---|---|---|
| | Type | Length | Break away (Snap off) | Length | Size (USP) | Insulation Color | Type | Length | Material |
| 8886259143 | SC | 44 mm | No | 24" (60 cm) | 3-0 | Clear | CV 23 | 17 mm | 455 Stainless Steel |
| 8886259243 | SC-2 | 60 mm | No | 24" (60 cm) | 3-0 | Clear | CV 23 | 17 mm | 455 Stainless Steel |
| 8886258643 | SC-6 | 88 mm | Yes | 24" (60 cm) | 3-0 | Clear | CV 23 | 17 mm | 455 Stainless Steel |
| 8886261753 | SC-6 | 88 mm | Yes | 24" (60 cm) | 2-0 | Orange | V-20 | 26 mm | 455 Stainless Steel |
| 8886262353 | SC-6 | 88 mm | Yes | 24" (60 cm) | 2-0 | White / Orange | V-20 | 26 mm | 455 Stainless Steel |
| 8886261553 | SC-6 | 88 mm | Yes | 24" (60 cm) | 2-0 | White | V-20 | 26 mm | 455 Stainless Steel |
| 8886259363 | SC-2 | 60 mm | No | 24" (60 cm) | 0 | Clear | CV 24 | 20 mm | 455 Stainless Steel |
| 8886259763 | SC-2 | 60 mm | No | 24" (60 cm) | 0 | Clear | V-20 | 26 mm | 455 Stainless Steel |
| 8886258963 | SC-6 | 88 mm | Yes | 24" (60 cm) | 0 | Clear | V-20 | 26 mm | 455 Stainless Steel |
| 8886258643-2 | SC-6 | 88 mm | Yes | 24" (60 cm) | 3-0 | Clear | CV 23 | 17 mm | 302 Stainless steel |
| 8886259143-2 | SC | 44 mm | No | 24" (60 cm) | 3-0 | Clear | CV 23 | 17 mm | 302 Stainless steel |
| 8886259243-2 | SC-2 | 60 mm | No | 24" (60 cm) | 3-0 | Clear | CV 23 | 17 mm | 302 Stainless steel |
| 8886259363-2 | SC-2 | 60 mm | No | 24" (60 cm) | 0 | Clear | CV 24 | 20 mm | 302 Stainless steel |

OXIVIT-MED

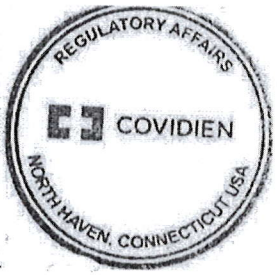
REGULATORY AFFAIRS COVIDIEN NORTH HAVEN, CONNECTICUT USA

Angela Van Arsdale
Angela Van Arsdale
Sr. Manager, Regulatory Affairs

**Standards List:**

| Standard/Directive | Year | Type | Title |
|---|---|---|---|
| EN ISO 10993-1 + AC | 2009 + 2010 | Biological Evaluation | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| EN ISO 10993-3 | 2014 | Biological Evaluation | Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity |
| EN ISO 10993-4 | 2017 | Biological Evaluation | Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood |
| EN ISO 10993-5 | 2009 | Biological Evaluation | Biological evaluation of medical devices part 5: Tests for In Vitro Cytotoxicity |
| EN ISO 10993-6 | 2016 | Biological Evaluation | Biological evaluation of medical devices — Part 6: Tests for local effects after implantation |
| EN ISO 10993-7 + AC | 2008 +2009 | Biological Evaluation | Biological evaluation of Medical Devices: Part 7 – Ethylene Oxide Sterilization Residuals |
| EN ISO 10993-10 | 2013 | Biological Evaluation | Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization |
| EN ISO 10993-11 | 2018 | Biological Evaluation | Biological evaluation of medical devices Part 11: Tests for systemic toxicity |
| EN ISO 10993-12 | 2012 | Biological Evaluation | Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials |
| EN ISO 15223-1 | 2016 | Labeling | Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements |
| EN 1041 + AC | 2008 + 2013 | Manufacturer Information | Information supplied by the manufacturer with medical devices. |
| EN ISO 14630 | 2012 | Medical Devices | Non-active surgical implants- General Requirements |
| EN ISO 13485 + AC | 2016 + 2016 | Quality Management | Medical devices. Quality management systems. Requirements for regulatory purposes. |
| IEC 62366-1 | 2015 | Risk Management | Medical devices – Application of usability engineering to medical devices (IEC 62366:2007) |
| EN ISO 14971 | 2012 | Risk Management | Medical devices. Application of risk management to medical devices. |
| EN 556-1 + AC | 2001 + 2006 | Sterility | Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices. |
| EN ISO 11135 | 2014 | Sterility | Medical Devices – Validation and routine control of ethylene oxide sterilization. |
| EN ISO 11607-1 | 2017 | Sterility | Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems |






Angela Van Arsdale
Angela Van Arsdale
Sr. Manager, Regulatory Affairs

**Standards List:**

| Standard/Directive | Year | Type | Title |
|---|---|---|---|
| EN ISO 11607-2 | 2017 | Sterility | Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing, and assembly processes. |
| EN ISO 11737-1 | 2018 | Sterility | Sterilization of medical devices - Microbiological methods – Part 1: Determination of the population of micro organisms on products. |
| EN ISO 11737-2 | 2009 | Sterility | Sterilization of medical device – Microbiological methods – Part 2: Test of sterility performed in the definition, validation and maintenance of a sterilization process |
| EN ISO 14644-1 | 2015 | Sterility | Cleanrooms and Associated Controlled Environments - Part 1: Classification of Air Cleanliness |
| EN ISO 14644-2 | 2015 | Sterility | Cleanrooms and Associated Controlled Environments - Part 2: Specifications for Testing and Monitoring to Prove Continued Compliance with ISO 14644-1 |
| EN ISO 14644-3 | 2005 | Sterility | Cleanrooms and associated controlled environments Part 3: Test methods |
| EN 60601-1 + A1 | 2006 + 2012 | Electrical | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance<br>Note: Subclause 56.3(c) is the only applicable section |

**List of Documents/Guidance Used for Guidance:**

| Standard/Directive Year Title | Year | Title |
|---|---|---|
| MEDDEV 2.7.1 | 2016 | European Commission Guidelines for Medical Devices – Evaluation of Clinical Data |
| USP Monograph – Absorbable/Nonabsorbable Surgical Suture | Current | Physical Test <861> Sutures – Diameter<br>Physical Test <871> Sutures – Needle Attachment<br>Physical Test <881> Tensile Strength |
| European Pharmacopeia | 2017 | 1/2008; 0324 Sutures, Sterile Non-Absorbable |



REGULATORY AFFAIRS COVIDIEN NORTH HAVEN, CONNECTICUT USA

Angela Van Arsdale
Angela Van Arsdale
Sr. Manager, Regulatory Affairs

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Product Service

# EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

**No. G7 077608 0044 Rev. 02**

**Manufacturer:**

**Covidien llc**
15 Hampshire Street
Mansfield, MA 02048
USA

**Product:**

**Non-Active Implants**
**Flexon™ Temporary Cardiac Pacing Lead**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

**Report no.:** 713173588

**Valid from:** 2020-03-25
**Valid until:** 2024-05-26

**Date,** 2020-03-25

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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TÜV SÜD Product Service

# EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

**No. G7 077608 0044 Rev. 02**

**Model(s):** **Flexon™ Temporary Cardiac Pacing Lead**

**Parameters:**

| Reorder Code | Straight Needle | | | Suture Wire | | | Curved Needle | | |
|---|---|---|---|---|---|---|---|---|---|
| | Type | Length | Break away (Snap off) | Length | Size (USP) | Insulation Color | Type | Length | Material |
| 8886259143 | SC | 44 mm | No | 24" (60 cm) | 3-0 | Clear | CV 23 | 17 mm | 455 Stainless Steel |
| 8886259243 | SC-2 | 60 mm | No | 24" (60 cm) | 3-0 | Clear | CV 23 | 17 mm | 455 Stainless Steel |
| 8886258643 | SC-6 | 88 mm | Yes | 24" (60 cm) | 3-0 | Clear | CV 23 | 17 mm | 455 Stainless Steel |
| 8886261753 | SC-6 | 88 mm | Yes | 24" (60 cm) | 2-0 | Orange | V-20 | 26 mm | 455 Stainless Steel |
| 8886262353 | SC-6 | 88 mm | Yes | 24" (60 cm) | 2-0 | White / Orange | V-20 | 26 mm | 455 Stainless Steel |
| 8886261553 | SC-6 | 88 mm | Yes | 24" (60 cm) | 2-0 | White | V-20 | 26 mm | 455 Stainless Steel |
| 8886259363 | SC-2 | 60 mm | No | 24" (60 cm) | 0 | Clear | CV 24 | 20 mm | 455 Stainless Steel |
| 8886259763 | SC-2 | 60 mm | No | 24" (60 cm) | 0 | Clear | V-20 | 26 mm | 455 Stainless Steel |
| 8886258963 | SC-6 | 88 mm | Yes | 24" (60 cm) | 0 | Clear | V-20 | 26 mm | 455 Stainless Steel |


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TÜV SÜD Product Service

# EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

**No. G7 077608 0044 Rev. 02**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8886258643-2 | SC-6 | 88 mm | Yes | 24" (60 cm) | 3-0 | Clear | CV 23 | 17 mm | 302 Stainless steel |
| 8886259143-2 | SC | 44 mm | No | 24" (60 cm) | 3-0 | Clear | CV 23 | 17 mm | 302 Stainless steel |
| 8886259243-2 | SC-2 | 60 mm | No | 24" (60 cm) | 3-0 | Clear | CV 23 | 17 mm | 302 Stainless steel |
| 8886259363-2 | SC-2 | 60 mm | No | 24" (60 cm) | 0 | Clear | CV 24 | 20 mm | 302 Stainless steel |


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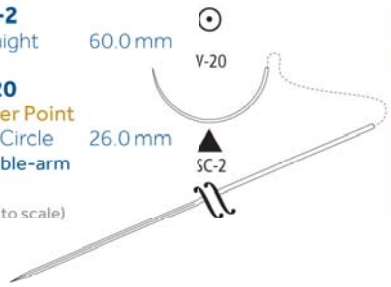
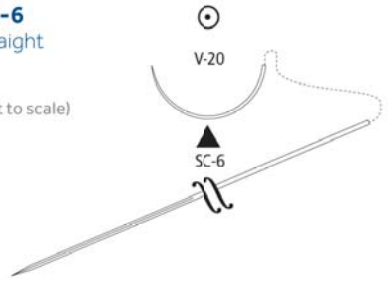
# Flexon™

## TAPER POINT

| Needles Specifications | Size USP | Size EP | Length cm | Length Inches | Color | Units Per box | Comments | Reorder code |
|---|---|---|---|---|---|---|---|---|
| **SC-2**<br>Straight 60.0 mm<br>**V-20**<br>Taper Point<br>1/2 Circle 26.0 mm<br>Double-arm<br>(Not to scale)<br>  | **0** | 3.5 | 60 | 24 | Undyed | 12 | | 88862597-63 |
| **SC-6**<br>Straight<br>(Not to scale)<br>  | **2-0** | 3 | 2 × 60 | 24 | 1 Orange<br>1 White | 12 | | 88862623-53 |
| | **2-0** | 3 | 60 | 24 | Orange | 12 | | 88862617-53 |
| | **2-0** | 3 | 60 | 24 | White | 12 | | 88862615-53 |
| | **0** | 3.5 | 60 | 24 | Undyed | 12 | | 88862589-63 |