



Benannt durch/Designated by
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 002374 0005 Rev. 00

Manufacturer:

BIOMETRIX LIMITED

4 Kiryat Mada
9145000 Jerusalem
ISRAEL

Product Category(ies):

Chest Drainage Systems, Drainage Systems, Non Active
Components of Physiological Blood Pressure Monitoring
Sets and Accessories, Cardioplegia: Tubing Systems and
Connectors for Cardiopulmonary Bypass, Angio Sets and
Accessories PTCA, Vascular Catheters, Drainage Catheters

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.:

IND2019061

Valid from:

2020-02-04

Valid until:

2024-05-26

Date,

2020-02-04

Christoph Dicks
Head of Certification/Notified Body



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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 002374 0005 Rev. 00

Facility(ies):

BIOMETRIX LIMITED
4 Kiryat Mada, 9145000 Jerusalem, ISRAEL

BIOMETRIX LIMITED
Pirhey Hahar 3, Har Tuv Industrial area B, 9900000 Bet Shemesh,
ISRAEL

Shomrat Molds LTD
Industrial Zone, 1030000 Hatzor Haglilit, ISRAEL

-/-



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Product Service

CERTYFIKAT EC

Zapewnienie pełnego systemu nadzoru jakości

Dyrektywa 93/42/EEC dla Urządzeń Medycznych (MDD), Aneks II wyłączając (4)

(Urządzenia w klasie IIa, IIb lub III)

numer G1 02374 0005 Rev. 00

Producent:

Biometrix Limited
4 Kiryat Mada
9145000 Jerozolima
Izrael

Kategorie produktów:

Systemy do drenażu klatki piersiowej, Systemy drenażu, Nieaktywne składniki zestawów i akcesoriów do monitorowania ciśnienia fizjologicznego
Kardioplegia: systemy linii i połączeń w krążeniu pozaustrojowym,
Zestawy do angiografii i akcesoria do PTCA, Cewniki naczyniowe, Cewniki do drenażu

Organ certyfikujący TUV SUD Product Service GmbH oświadcza, iż wskazany producent zastosował pełen system zapewnienia jakości dla projektu, wytwarzania i końcowej inspekcji dla poszczególnych produktów / kategorii produktowych zgodnie z Dyrektywą MDD Aneks II. System zapewnienia jakości jest zgodny z wymogami tej dyrektywy i jest poddany okresowemu nadzorowi. W celach marketingowych dla urządzeń klasy III dodatkowy Aneks II (4) jest wymagany. Patrz również na odwrocie.

Nr raportu: IND2019061

Ważny od: 2020-02-04

Ważny do: 2024-05-26

Data: 2020-02-04

Podpis nieczytelny

Christoph Dicks

kierownik certyfikacji / Jednostki Notyfikowanej



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Product Service

CERTYFIKAT EC

Zapewnienie pełnego systemu nadzoru jakości

Dyrektywa 93/42/EEC dla Urządzeń Medycznych (MDD), Aneks II wyłączając (4)
(Urządzenia w klasie IIa, IIb lub III)

numer G1 02374 0005 Rev. 00

Zakłady:

Biometrix Limited

4 Kiryat Mada, 9145000 Jerozolima, Izrael

Biometrix Limited

Pirhey Hahar 3, Har Tuv Industrial area B, 9900000 Bet Shemesh,
Izrael

Shomrat Molds LTD

Industrial Zone, 1030000 Hatzor Haglilit, Izrael



DECLARATION OF CONFORMITY TO THE MEDICAL DEVICE DIRECTIVE

MDD 93/42EEC as amended by 2007/47EC

Authorized Representative.

Biometrix SRO
Vicenzy 16S
Samorin, 93101
Slovakia
SRN: SK-AR-000002253

Notified body:

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 MÜNCHEN
Germany

Manufacturer Name and Address:

Biometrix LIMITED
4 Kiryat Mada
9145000 Jerusalem
Israel
SRN: IL-MF-000010010

Importer:

Biometrix SRO
Vicenzy 16S
Samorin , 93101
Slovakia
SRN:SK-IM-000003112

Certificate No: G1 002374 0005 **(Exp. Date):**2024-05-26

Product family: Vascular Catheters and Accessories

Products sub-groups: CVC sets and High-Flow

Classification: Class IIb, Rule 7


Intended Use: For short-term Central Venous Catheterization in jugular, subclavian or femoral veins and for High-flow infusion of different solutions in emergency situations

GMDN Code: 61594

CND Code: C0102, A0303

Reference: **CQMP548 Medical Device Approval**

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Approved by: Tali Raz, QA/RA Director	Date: 26/10/2021	Signature: 
--	------------------	--

Applicable Standards: 11-005 REV01 list of standards TF 6.01

Herewith to declare that:

Above-mentioned product complies with Annex II excluding 4 of the Medical Device Directive, MDD 93/42/EEC as amended by 2007/47/EC. All supporting documentation is held by the manufacturer.

Biometrix LIMITED is exclusively responsible for the Declaration of Conformity.

List of devices is enclosed in Appendix A.

Zuzana Vavreková

A handwritten signature in blue ink, appearing to be "Zuzana Vavreková", written over a horizontal line.


RA Manager

30.10.2021

Date

Reference: **CQMP548 Medical Device Approval**

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Approved by: Tali Raz, QA/RA Director	Date: 26/10/2021	Signature: 
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Appendix A - List of devices:

List of Devices for Central Venous Catheter & High Flow:

Device description	Ref #
8.5fr X 15cm Quadro Lumen CVC Set	HH-8515
8.5fr X 20cm Quadro Lumen CVC Set	HH-8520
8.5Fr X 30cm Quadro Lumen CVC Set	HH-8530
8.5Fr X 15cm Quadro Lumen CVC Set	HH-I8515
8.5Fr X 20cm Quadro Lumen CVC Set	HH-I8520
8.5Fr X 30cm Quadro Lumen CVC Set	HH-I8530
8.5FrX15cm 4Lumen CVC Set,Nitinol GW,Selding.Syr	HH-R8516
8.5FrX20cm 4Lumen CVC Set,Nitinol GW,Selding.Syr	HH-R8521
8.5FrX30cm 4Lumen CVC Set,Nitinol GW,Selding.Syr	HH-R8531
5.5frX8cm Triple Lumen CVC Set	HJ-5008
5.5frX13cm Triple Lumen CVC Set	HJ-5013
5.5frX30cm Triple Lumen CVC Set	HJ-5030
7fr X 15cm Triple Lumen CVC Set	HJ-7015
7fr X 20cm Triple Lumen CVC Set	HJ-7020
7fr X 30cm Triple Lumen CVC Set	HJ-7030
7FrX15cm Triple Lumen CVC Set	HJ-A7015
5.5frX8cm Triple Lumen CVC Set	HJ-E5008
5.5frX13cm Triple Lumen CVC Set	HJ-E5013
5.5frX30cm Triple Lumen CVC Set	HJ-E5030
7FrX15cm Triple Lumen CVC Set	HJ-E7015
7FrX20cm Triple Lumen CVC Set	HJ-E7020
7FrX30cm Triple Lumen CVC Set	HJ-E7030
8.5frX15cm Triple Lumen CVC Set w/Y-Needle	HJ-I8515
8.5frX20cm Triple Lumen CVC Set w/Y-Needle	HJ-I8520
5.5frX8cm 3Lumen CVC Set,Nitinol GW,Selding.Syr.	HJ-R5008
5.5frX13cm 3Lumen CVC Set,Nitinol GW,Selding.Syr	HJ-R5013
7FrX15cm 3Lumen CVC Set,Nitinol GW,Selding.Syr.	HJ-R7016
7FrX20cm 3Lumen CVC Set,Nitinol GW,Selding.Syr.	HJ-R7021
7FrX30cm 3Lumen CVC Set,Nitinol GW,Selding.Syr.	HJ-R7031
8.5FrX15cm 3Lumen CVC Set,Nitinol GW,Selding.Syr	HJ-R8516
8.5FrX20cm 3Lumen CVC Set,Nitinol GW,Selding.Syr	HJ-R8521
4frX5cm Double Lumen CVC Set	HK-4005
4FrX8cm Pediatric Double Lumen CVC Set	HK-4008
4frX13cm Double Lumen CVC Set	HK-4013
4FrX30cm Pediatric Double Lumen CVC Set	HK-4030
5frX6cm Double Lumen CVC Set	HK-5006
5frX8cm Double Lumen CVC Set	HK-5008
5frX13cm Double Lumen CVC Set	HK-5013
5FrX20cm Double Lumen CVC Set	HK-5020
5fr X 30cm Pediatric Double Lumen CVC Set	HK-5030
7frX15cm Double Lumen CVC Set	HK-7015

Reference: **CQMP548 Medical Device Approval**


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Approved by: Tali Raz, QA/RA Director	Date: 26/10/2021	Signature: 
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7frX20cm Double Lumen CVC Set	HK-7020
7frX30cm Double Lumen CVC Set	HK-7030
4FrX5cm Pediatric Double Lumen CVC Set	HK-E4005
4FrX8cm Pediatric Double Lumen CVC Set	HK-E4008
4FrX13cm Pediatric Double Lumen CVC Set	HK-E4013
5FrX6cm Pediatric Double Lumen CVC Set	HK-E5006
5frX8cm Double Lumen CVC Set	HK-E5008
5FrX13cm Pediatric Double Lumen CVC Set	HK-E5013
7FrX15cm Double Lumen CVC Set	HK-E7015
7FrX20cm Double Lumen CVC Set	HK-E7020
7FrX30cm Double Lumen CVC Set	HK-E7030
7frX15cm Double Lumen CVC Set	HK-E7115
4FrX5cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R4005
4FrX8cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R4008
4FrX13cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R4013
4FrX30cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R4030
5FrX6cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R5006
5FrX8cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R5008
5FrX13cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R5013
5FrX20cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R5020
5FrX30cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R5030
7FrX15cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R7016
7FrX20cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R7021
7FrX30cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R7031
14Ga x 15cm Single Lumen CVC Set	HO-4015
14Ga x 20cm Single Lumen CVC Set	HO-4020
14Ga x 30cm Single Lumen CVC Set	HO-4030
16Ga x 15cm Single Lumen CVC Set	HO-6015
16Ga x 20cm Single Lumen CVC Set	HO-6020
16Gax30cm Single Lumen CVC Set	HO-6030
24Ga x 8cm Single Lumen CVC Set	HO-7008
24Ga x 15cm Single Lumen CVC Set	HO-7015
24Ga x 20cm Single Lumen CVC Set	HO-7020
18Ga x15cm Single Lumen CVC Set	HO-8015
18Ga x20cm Single Lumen CVC Set	HO-8020
20Ga x10cm Single Lumen CVC Set	HO-9010
20Ga x13cm Single Lumen CVC Set	HO-9013
20Ga x15cm Single Lumen CVC Set	HO-9015
20Ga x20cm Single Lumen CVC Set	HO-9020
14Ga x15cm Single Lumen CVC Set	HO-A4015
14Ga x 15cm Single Lumen CVC Set	HO-E4015
14Ga x 20cm Single Lumen CVC Set	HO-E4020
14Ga x 30cm Single Lumen CVC Set	HO-E4030
16Ga x 15cm Single Lumen CVC Set	HO-E6015
16Ga x 20cm Single Lumen CVC Set	HO-E6020
16Ga x 30cm Single Lumen CVC Set	HO-E6030

Reference: **CQMP548 Medical Device Approval**

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Approved by: Tali Raz, QA/RA Director	Date: 26/10/2021	Signature: 
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14Gax15cm 1Lumen CVC Set,Nitinol GW,Selding.Syr.	HO-R4016
14GaX20cm 1Lumen CVC Set,Nitinol GW,Selding.Syr.	HO-R4021
14GaX30cm 1Lumen CVC Set,Nitinol GW,Selding.Syr.	HO-R4031
16GaX15cm 1Lumen CVC Set,Nitinol GW,Selding.Syr.	HO-R6016
16GaX20cm 1Lumen CVC Set,Nitinol GW,Selding.Syr.	HO-R6021
16GaX30cm 1Lumen CVC Set,Nitinol GW,Selding.Syr.	HO-R6031
24GaX8cm 1Lumen CVC Set,Nitinol GW,Selding.Syr.	HO-R7008
24GaX15cm 1Lumen CVC Set,Nitinol GW,Selding.Syr.	HO-R7015
18GaX15cm 1Lumen CVC Set,Seldinger Syringe	HO-R8016
18GaX20cm 1Lumen CVC Set,Seldinger Syringe	HO-R8021
20GaX10cm 1Lumen CVC Set,Seldinger Syringe	HO-R9010
20GaX15cm 1Lumen CVC Set,Seldinger Syringe	HO-R9015
8Fr X 10Cm Vessel Dilato	HS-0101
11Fr X 15Cm Vessel Dilator	HS-0201
9Fr X 10Cm Vessel Dilator	HS-0301
Seldinger Technique Supporting Set	HY-1000
Trauma Pack	JC-7100
8fr Rapid Infusion Catheter Set	JD-X4062

End of list

Reference: **CQMP548 Medical Device Approval**

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Approved by: Tali Raz, QA/RA Director	Date: 26/10/2021	Signature: 
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Deklaracja zgodności z dyrektywą dot. wyrobów medycznych

MDD 93/42EEC zastąpiona przez 2007/47EC

Autoryzowany przedstawiciel:

Biometrix SRO
Vicenzy 16S
Samorin, 93101 Slovakia
SRN: SK-AR-000002253

Jednostka notyfikowana:

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 MÜNCHEN
Germany

Producent nazwa i adres:

Biometrix LIMITED
4 Kiryat Mada
9145000 Jerusalem
Israel
SRN: IL-MF-000010010

Importer:

Biometrix SRO
Vicenzy 16S
Samorin , 93101
Slovakia
SRN:SK-IM-000003112

Nr certyfikatu: G1 002374 0005 (Data ważności):2024-05-26

Rodzina produktów: Cewniki naczyniowe i akcesoria

Podgrupy produktów: Zestawy CVC i High-Flow

Klasyfikacja: Klasa IIb, reguła 7

Przeznaczenie: Do krótkotrwałego cewnikowania żył centralnych w żyłach szyjnych, podobojczykowych lub udowych oraz do wysokoprzepływowego wlewu różnych roztworów w sytuacjach awaryjnych.

GMDN Code: 61594

CND Code: C0102, A0303

Reference: CQMP548 Medical Device Approval

Od nr: 431	Rev: 03	Deklaracja Zgodności MDD 93/42EEC	Strona 1 z 5
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Zatwierdzone przez: Tali Raz Dyrektor QA/RA	Data: 26/10/2021	Podpis: <i>podpis nieczytelny</i>
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Obowiązujące normy: 11-005 REV01 lista norm TF 6.01

Niniejszym oświadczam, że:

Wyżej wymieniony produkt jest zgodny z Załącznikiem II z wyłączeniem 4 Dyrektywy o Wyrobach Medycznych, MDD 93/42/EEC, zmienionej przez 2007/47/EC. Cała dokumentacja pomocnicza jest w posiadaniu producenta.

Biometrix LIMITED ponosi wyłączną odpowiedzialność za Deklarację Zgodności.

Wykaz wyrobów znajduje się w Załączniku A.

Zuzana Vavreková 30.10.2021

Podpis nieczytelny

Kierownik RA Data

Reference: CQMP548 Medical Device Approval

Od nr: 431	Rev: 03	Deklaracja Zgodności MDD 93/42EEC	Strona 2 z 5
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Zatwierdzone przez: Tali Raz Dyrektor QA/RA	Data: 26/10/2021	Podpis: <i>podpis nieczytelny</i>
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Załącznik A – lista wyrobów

Lista wyrobów – zestawy cewników do żył centralnych i High-Flow

Device description	Ref #
8.5fr X 15cm Quadro Lumen CVC Set	HH-8515
8.5fr X 20cm Quadro Lumen CVC Set	HH-8520
8.5Fr X 30cm Quadro Lumen CVC Set	HH-8530
8.5Fr X 15cm Quadro Lumen CVC Set	HH-I8515
8.5Fr X 20cm Quadro Lumen CVC Set	HH-I8520
8.5Fr X 30cm Quadro Lumen CVC Set	HH-I8530
8.5FrX15cm 4Lumen CVC Set,Nitinol GW,Selding.Syr	HH-R8516
8.5FrX20cm 4Lumen CVC Set,Nitinol GW,Selding.Syr	HH-R8521
8.5FrX30cm 4Lumen CVC Set,Nitinol GW,Selding.Syr	HH-R8531
5.5frX8cm Triple Lumen CVC Set	HJ-5008
5.5frX13cm Triple Lumen CVC Set	HJ-5013
5.5frX30cm Triple Lumen CVC Set	HJ-5030
7fr X 15cm Triple Lumen CVC Set	HJ-7015
7fr X 20cm Triple Lumen CVC Set	HJ-7020
7fr X 30cm Triple Lumen CVC Set	HJ-7030
7FrX15cm Triple Lumen CVC Set	HJ-A7015
5.5frX8cm Triple Lumen CVC Set	HJ-E5008
5.5frX13cm Triple Lumen CVC Set	HJ-E5013
5.5frX30cm Triple Lumen CVC Set	HJ-E5030
7FrX15cm Triple Lumen CVC Set	HJ-E7015
7FrX20cm Triple Lumen CVC Set	HJ-E7020
7FrX30cm Triple Lumen CVC Set	HJ-E7030
8.5frX15cm Triple Lumen CVC Set w/Y-Needle	HJ-I8515
8.5frX20cm Triple Lumen CVC Set w/Y-Needle	HJ-I8520
5.5frX8cm 3Lumen CVC Set,Nitinol GW,Selding.Syr.	HJ-R5008
5.5frX13cm 3Lumen CVC Set,Nitinol GW,Selding.Syr	HJ-R5013
7FrX15cm 3Lumen CVC Set,Nitinol GW,Selding.Syr.	HJ-R7016
7FrX20cm 3Lumen CVC Set,Nitinol GW,Selding.Syr.	HJ-R7021
7FrX30cm 3Lumen CVC Set,Nitinol GW,Selding.Syr.	HJ-R7031
8.5FrX15cm 3Lumen CVC Set,Nitinol GW,Selding.Syr	HJ-R8516
8.5FrX20cm 3Lumen CVC Set,Nitinol GW,Selding.Syr	HJ-R8521
4frX5cm Double Lumen CVC Set	HK-4005
4FrX8cm Pediatric Double Lumen CVC Set	HK-4008
4frX13cm Double Lumen CVC Set	HK-4013
4FrX30cm Pediatric Double Lumen CVC Set	HK-4030
5frX6cm Double Lumen CVC Set	HK-5006
5frX8cm Double Lumen CVC Set	HK-5008
5frX13cm Double Lumen CVC Set	HK-5013
5FrX20cm Double Lumen CVC Set	HK-5020
5fr X 30cm Pediatric Double Lumen CVC Set	HK-5030
7frX15cm Double Lumen CVC Set	HK-7015

Reference: CQMP548 Medical Device Approval

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Zatwierdzone przez: Tali Raz Dyrektor QA/RA	Data: 26/10/2021	Podpis: <i>podpis nieczytelny</i>
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7frX20cm Double Lumen CVC Set	HK-7020
7frX30cm Double Lumen CVC Set	HK-7030
4FrX5cm Pediatric Double Lumen CVC Set	HK-E4005
4FrX8cm Pediatric Double Lumen CVC Set	HK-E4008
4FrX13cm Pediatric Double Lumen CVC Set	HK-E4013
5FrX6cm Pediatric Double Lumen CVC Set	HK-E5006
5frX8cm Double Lumen CVC Set	HK-E5008
5FrX13cm Pediatric Double Lumen CVC Set	HK-E5013
7FrX15cm Double Lumen CVC Set	HK-E7015
7FrX20cm Double Lumen CVC Set	HK-E7020
7FrX30cm Double Lumen CVC Set	HK-E7030
7frX15cm Double Lumen CVC Set	HK-E7115
4FrX5cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R4005
4FrX8cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R4008
4FrX13cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R4013
4FrX30cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R4030
5FrX6cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R5006
5FrX8cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R5008
5FrX13cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R5013
5FrX20cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R5020
5FrX30cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R5030
7FrX15cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R7016
7FrX20cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R7021
7FrX30cm 2Lumen CVC Set,Nitinol GW,Selding.Syr.	HK-R7031
14Ga x 15cm Single Lumen CVC Set	HO-4015
14Ga x 20cm Single Lumen CVC Set	HO-4020
14Ga x 30cm Single Lumen CVC Set	HO-4030
16Ga x 15cm Single Lumen CVC Set	HO-6015
16Ga x 20cm Single Lumen CVC Set	HO-6020
16Gax30cm Single Lumen CVC Set	HO-6030
24Ga x 8cm Single Lumen CVC Set	HO-7008
24Ga x 15cm Single Lumen CVC Set	HO-7015
24Ga x 20cm Single Lumen CVC Set	HO-7020
18Ga x15cm Single Lumen CVC Set	HO-8015
18Ga x20cm Single Lumen CVC Set	HO-8020
20Ga x10cm Single Lumen CVC Set	HO-9010
20Ga x13cm Single Lumen CVC Set	HO-9013
20Ga x15cm Single Lumen CVC Set	HO-9015
20Ga x20cm Single Lumen CVC Set	HO-9020
14Ga x15cm Single Lumen CVC Set	HO-A4015
14Ga x 15cm Single Lumen CVC Set	HO-E4015
14Ga x 20cm Single Lumen CVC Set	HO-E4020
14Ga x 30cm Single Lumen CVC Set	HO-E4030
16Ga x 15cm Single Lumen CVC Set	HO-E6015
16Ga x 20cm Single Lumen CVC Set	HO-E6020
16Ga x 30cm Single Lumen CVC Set	HO-E6030

Reference: CQMP548 Medical Device Approval

Od nr: 431	Rev: 03	Deklaracja Zgodności MDD 93/42EEC	Strona 4 z 5
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Zatwierdzone przez: Tali Raz Dyrektor QA/RA	Data: 26/10/2021	Podpis: <i>podpis nieczytelny</i>
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14Gax15cm 1Lumen CVC Set,Nitinol GW,Selding.Syr.	HO-R4016
14GaX20cm 1Lumen CVC Set,Nitinol GW,Selding.Syr.	HO-R4021
14GaX30cm 1Lumen CVC Set,Nitinol GW,Selding.Syr.	HO-R4031
16GaX15cm 1Lumen CVC Set,Nitinol GW,Selding.Syr.	HO-R6016
16GaX20cm 1Lumen CVC Set,Nitinol GW,Selding.Syr.	HO-R6021
16GaX30cm 1Lumen CVC Set,Nitinol GW,Selding.Syr.	HO-R6031
24GaX8cm 1Lumen CVC Set,Nitinol GW,Selding.Syr.	HO-R7008
24GaX15cm 1Lumen CVC Set,Nitinol GW,Selding.Syr.	HO-R7015
18GaX15cm 1Lumen CVC Set,Seldinger Syringe	HO-R8016
18GaX20cm 1Lumen CVC Set,Seldinger Syringe	HO-R8021
20GaX10cm 1Lumen CVC Set,Seldinger Syringe	HO-R9010
20GaX15cm 1Lumen CVC Set,Seldinger Syringe	HO-R9015
8Fr X 10Cm Vessel Dilato	HS-0101
11Fr X 15Cm Vessel Dilator	HS-0201
9Fr X 10Cm Vessel Dilator	HS-0301
Seldinger Technique Supporting Set	HY-1000
Trauma Pack	JC-7100
8fr Rapid Infusion Catheter Set	JD-X4062

Koniec listy

Reference: CQMP548 Medical Device Approval

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Zatwierdzone przez: Tali Raz Dyrektor QA/RA	Data: 26/10/2021	Podpis: <i>podpis nieczytelny</i>
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