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GUOYU GLOBAL, INC.

INFUSION SETS FOR SINGLE USE

FDA U.S. FOOD & DRUG ADMINISTRATION

TÜV SÜD PSB Singapore

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INFUSION SETS FOR SINGLE USE

SMALL CHAMBER INFUSION SET

Description	20 Drops, Latex free "Y" injection site Luer lock with needle 21G x 1 1/2"
Package	PE Bag or Blister
PE Bag (Units)	25
Case (units)	500
Carton Size	65*38*33cm
Sterilization	Ethylene Oxide
Shelf Life	3 years

BIG CHAMBER INFUSION SET

Description	20 Drops, Latex free "Y" injection site Luer lock with needle 21G x 1 1/2"
Package	PE Bag or Blister
PE Bag (Units)	25
Case (units)	400
Carton Size	58*39*37cm
Sterilization	Ethylene Oxide
Shelf Life	3 years

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INFUSION SETS FOR SINGLE USE

IMG-6730	ILLUSTRATION
SM-001	
SM-002	
SM-003	

Small chamberInfusion Sets （WG-IS-001）

Air-vented spike

- For Infusion bags With solution filter
- 20 Drops=1±0.1ml
- Flexible Drip Chamber(__6_ml)
- Roller Clamp
- Slip or Lock Adapter
- YInjection Site(Latex or Latex free)
- For Gravity Use
- without needle
- Sterile

IMG-6735	ILLUSTRATION
SM-004	
SM-005	
SM-006	

Small chamberInfusion Sets （WG-IS-001）

Air-vented spike

- For Infusion bags and bottle With solution filter
- 20 Drops=1±0.1ml
- Flexible Drip Chamber(__6_ml)
- Roller Clamp
- Slip or Lock Adapter
- Y-site Injection(Latex or Latex free)
- For Gravity Use
- With needle
- Sterile

IMG-6764	ILLUSTRATION
SM-007	
SM-008	
SM-009	

Small ChamberInfusion Sets （WG-IS-001）

Air-vented spike

- For Infusion bags With solution filter
- 20 Drops=1±0.1ml
- Flexible Drip Chamber
- Roller Clamp
- Slip or Lock Adapter
- Latex/Latex-free Y Injection Site With/ without needle
- For Gravity Use
- Sterile

IMG-6767	ILLUSTRATION
SM-010	
SM-011	
SM-012	

Small ChamberInfusion Sets （WG-IS-001）

Air-vented spike

- For Infusion bags With solution filter
- 20 Drops=1±0.1ml
- Flexible Drip Chamber
- Roller Clamp
- Slip or Lock Adapter
- Latex/Latex-free Y Injection Site With/ without needle
- For Gravity Use
- Sterile

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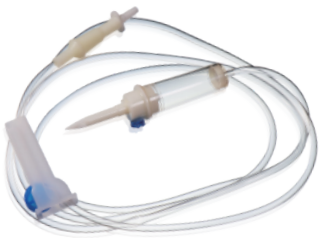
INFUSION SETS FOR SINGLE USE

IMG-6782	ILLUSTRATION
SM-013	
SM-014	
SM-015	

Small ChamberInfusion Sets （WG-IS-001）

Air-vented spike

- For Infusion bags With solution filter
- 20 Drops=1±0.1ml
- Flexible Drip Chamber
- Roller Clamp
- Slip or Lock Adapter
- Latex Injection Site With/ without needle
- For Gravity Use
- Sterile

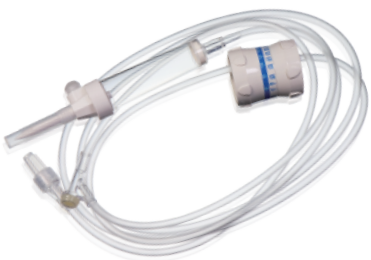


IMG-6802	ILLUSTRATION
SM-016	
SM-017	
SM-018	

Small ChamberInfusion Sets （WG-IS-001）

Air-vented spike

- For Infusion bags With solution filter
- 20 Drops=1±0.1ml
- Flexible Drip Chamber
- Roller Clamp
- Slip or Lock Adapter
- Latex/Latex-free YInjection Site With/ without needle
- For Gravity Use
- Sterile

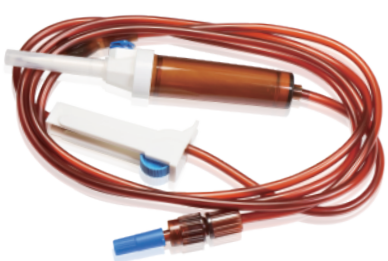


IMG-6744	ILLUSTRATION
BI-001	
BI-002	
BI-003	

Big ChamberInfusion Sets （WG-IS-001）

With air-vent spike

- For Infusion bags/bottle
- 20 Drops=1±0.1ml With solution filter
- Flexible Drip Chamber(___ml,___cm)
- Precision regulator
- Slip or Lock Adapter
- Latex/Latex-free YInjection Site With/ without needle
- For Gravity Use
- Sterile



IMG-6825	ILLUSTRATION
BI-004	
BI-005	
BI-006	

Big ChamberInfusion Sets （WG-IS-001）

Air-vented spike Light-proof type

- For Infusion bags With solution filter
- 20 Drops=1±0.1ml
- Flexible Drip Chamber
- ABSRoller Clamp
- Slip or Lock Adapter
- Latex/Latex-free YInjection Site With/ without needle
- For Gravity Use
- Sterile

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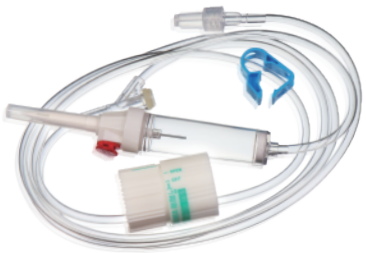
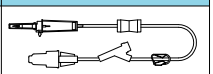
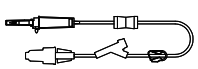
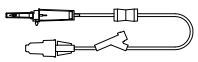
INFUSION SETS FOR SINGLE USE

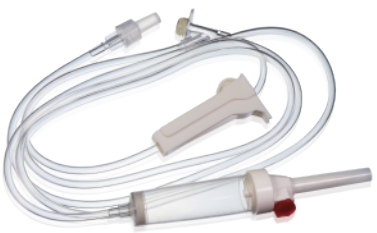


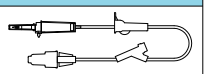
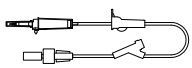
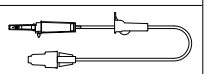
IMG-6757	ILLUSTRATION
BI-007	
BI-008	
BI-009	

Big ChamberInfusion Sets （WG-IS-001）

Air-vented spike

- For Infusion bags With solution filter
- 60 Drops=1±0.1ml
- Flexible Drip Chamber
- With Clip
- Slip or Lock Adapter
- Latex/Latex-free YInjection Site With/ without needle
- For Gravity Use
- Sterile

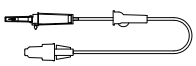
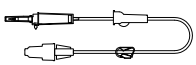
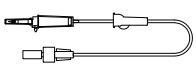


IMG-6806	ILLUSTRATION
BI-010	
BI-011	
BI-012	

Big ChamberInfusion Sets （WG-IS-001）

Air-vented spike

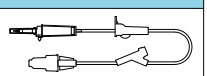
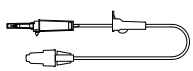
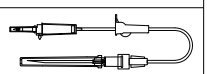
- For Infusion bags With solution filter
- 20 Drops=1±0.1ml
- Flexible Drip Chamber
- Roller Clamp
- Slip or Lock Adapter
- Protecting type,Latex/Latex-free YInjection Site With/ without needle
- For Gravity Use
- Sterile

IMG-6748	ILLUSTRATION
IN-001	
IN-002	
IN-003	

Infusion Sets （WG-IS-001）

Without air-vent spike

- For Infusion bags With solution filter
- 20 Drops=1±0.1ml
- Flexible Drip Chamber(__6_ml)
- Roller Clamp
- Slip or Lock Adapter
- For Gravity Use With/ without needle
- For Gravity Use
- Sterile

IMG-6835	ILLUSTRATION
IN-004	
IN-005	
IN-006	

Infusion Sets （WG-IS-001）

- For Infusion bags
- 20 Drops=1±0.1ml
- Flexible Drip Chamber
- Roller Clamp
- Slip or Lock Adapter
- Latex/Latex-free Injection Site
- For Gravity Use
- Sterile

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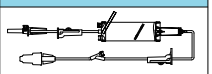
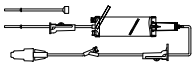
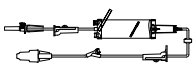
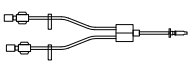
INFUSION SETS FOR SINGLE USE

IMG-6846	ILLUSTRATION
SO-001	
SO-002	
SO-003	

Soft burette

- 100 and 150ml Graduated Burette With Shut-off Valve
- 60 Drops=1±0.1ml
- Flexible Drip Chamber with Filter
- Roller Clamp
- Slip or Lock Adapter with Protective Cap
- Latex/Late-free Y Injection Site With/ without needle
- For Gravity Use
- Sterile

IMG-6775	ILLUSTRATION
IN-007	

Infusion Sets（WG-IS-001）

- For Infusion bags
- 20 Drops=1±0.1ml
- Flexible Drip Chamber
- Roller Clamp
- Slip or Lock Adapter
- Latex/Latex-free Injection Site
- For Gravity Use
- Sterile

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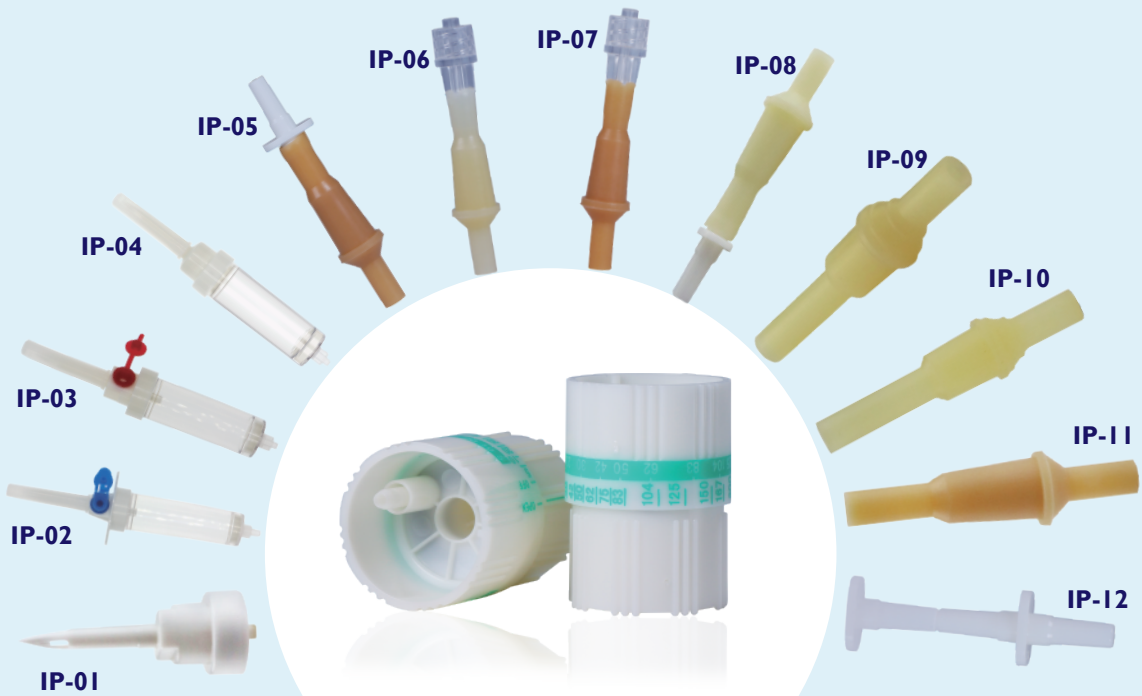
INFUSION SETS FOR SINGLE USE

SPARE PARTS FOR INFUSION SET



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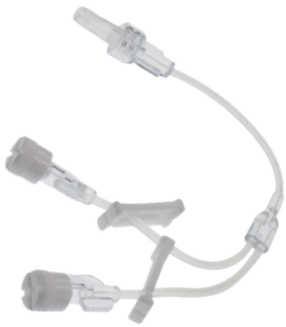
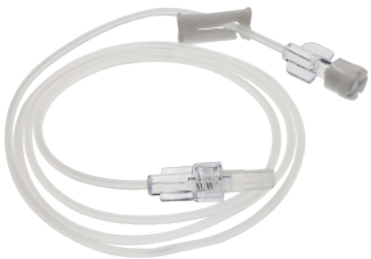
INFUSION SETS FOR SINGLE USE

SPARE PARTS FOR INFUSION SET



Extension Set（WG-IS-001）
■ 7" (18 cm), Appx 0.3mL
■ Smallbore, fixed male luer lock, Clamp,
non-DEHP
■ 0.8mm x 2.4mm

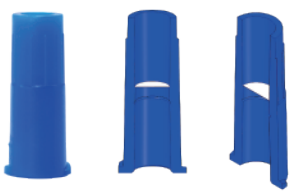


Extension Set（WG-IS-001）
■ 36" (91cm), Appx 3.8mL
■ Microbore Ext Set with Clamp, Fixed
Male Luer, non-DEHP
■ 0.8mm x 2.4mm

Extension Set（WG-IS-001）
■ 5" (12 cm), Appx 0.3 mL
■ Microbore, T-Connector, Clamp,
non-DEHP

TJQ62-3

TJQ62-3



Water blocking Protective cap

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INFUSION SETS FOR SINGLE USE

SPARE PARTS FOR INFUSION SET

Y-injection port


YP-01


YP-02


YP-03


YP-04


YP-05

Flow regulator


FR-01


FR-02


FR-03


FR-04


FR-05

Fhree-way valve


FWV-01


FWV-02


FWV-03

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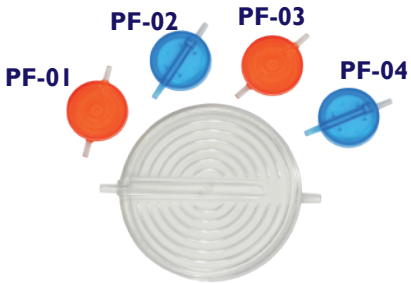
INFUSION SETS FOR SINGLE USE

SPARE PARTS FOR INFUSION SET

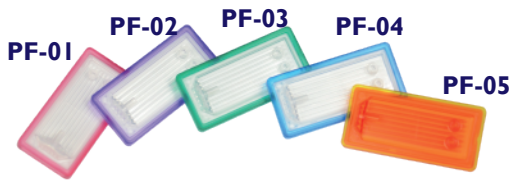
HC-01 HC-02 HC-03 HC-04 HC-05 HC-06

Exhaust valve

EV-01 EV-02



Precision filter



Precision filter

INFUSION SETS FOR SINGLE USE

New Search | Back To Search Results

Device Classification Name	Set, Administration, Intravascular
510(K) Number	K090012
Device Name	DISPOSABLE INFUSION SET
Applicant	SHAN DONG WEI GAO GROUP MEDICAL POLYMER PRODUCTS STE.8D, ZHONGXIN ZHONGSHAN MANSION,NO.19, LANE 999, ZHONG Shan Nan Er Rd., Shanghai, CN 200030
Applicant Contact	Diana Hong
Correspondent	SHAN DONG WEI GAO GROUP MEDICAL POLYMER PRODUCTS STE.8D, ZHONGXIN ZHONGSHAN MANSION,NO.19, LANE 999, ZHONG Shan Nan Er Rd., Shanghai, CN 200030
Correspondent Contact	Diana Hong
Regulation Number	880.5440
Classification Product Code	FPA
Date Received	01/02/2009
Decision Date	06/11/2009
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No
Recalls	CDRH Recalls

K090012

Weigao Group

Chapter III 510(k) Summary

The assigned 510(k) Number is: _____ JUN 11 2009

1. Date Prepared: December 31, 2008

2. Sponsor Information

ShanDong WeiGao Group Medical Polymer Co., Ltd
No.312 Shichang Road
Weihai City, Shangdong, China

Contact Person: Mrs. Zhao Suxia, Quality Manager
Tel: +86-631-5621632
Fax: +86-631-5620555
E-Mail: Zsx9001@sina.com

3. Submission Correspondent

Ms. Diana Hong
Mr. Lee Fu
Shanghai Mid-Link Business Consulting Co., Ltd
Suite 8D, Zhongshan Zhongxin Mansion
No.19, Lane 999, Zhongshan No.2 Road(S)
Shanghai, 200030, China

4. Device Name and Classification:

Device Trade Name: Disposable infusion set
Device Common Name: Disposable infusion device
Device Classification Name: Set, administration, intravascular
Product Code: FPA
Regulation Number: 880.5440
Device Class: II

5. Predicate Device Identification:

K060082

Weigao Group

Tianjin Medis Disposable Infusion Set
K-number: K060082

6. Intended Use:

Disposable infusion set is used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

7. Device Description:

The applicant device is plastic, single-use, sterile disposable infusion device, which is intended to be used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

The protective cap o is intended to protect the needle; The puncturing needle is made of Polyethylene and used to pierce the container; the catheter is made of Polyvinyl chloride and used to connect various components, there is no DEHP used in the proposed device; the drip is transparent so that the user can observe the dropping condition of the medical solution, and it has a filtration mesh which can prevent the micro particle with diameter larger than 200 um to from entering human vessel; Flow regulator is used to adjust the flow rate from zero to maximum; Infusion needle is inserted into human vessel for medical solution transfusion, it is made of stainless steel.

The proposed device is provided sterilized.

8. Test Conclusion resignation

Laboratory testing was conducted to validate and verify that disposable infusion set met all design specifications and was substantially equivalent to the predicate device.

9. Substantially Equivalent Conclusion:
The subject device, disposable infusion set is substantially equivalent to the predicate device.

FDA U.S. FOOD & DRUG ADMINISTRATION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 11 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Shan Dong Wei Gao Group Medical Polymer Products
C/O Ms. Diana Hong
General Manager
Shanghai Midlink Business Consulting Company, Limited
Suite 8D, No. 19, Line 999,
Zhongshan No.2 Road (S)
Shanghai, 200030,
CHINA

Re: K090012
Trade/Device Name: Disposable Infusion set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: May 21, 2009
Received: May 26, 2009

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090012

Indication for Use

510(k) Number:

Device Name: Disposable Infusion Set

Indications for Use:

Disposable Infusion Set is used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

Prescription Use __√__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K090012

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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TÜV SÜD 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 094273 0003 Rev. 03

Manufacturer: **Shandong Weigao Group Medical Polymer Co., Ltd.**
No.18 Xingshan Road
Torch Hi-tech Science Park
264210 Weihai, Shandong Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Sterile 'Infusion Sets, Transfusion Sets, Hypodermic Syringes, Plastic Blood Bag, Intravenous Needles, Blood Collection Needles, High Pressure Angiographic Syringes, Retractable Auto-Disable Syringe, Oral / Enteral Syringe' for Single Use, Sterile Micro-Filter Syringes for Single Use, Infusion Sets with Precision Filters for Single Use, Light-resistant Infusion Sets for Single Use, Flow Rate-setting and Adjustable Infusion Sets with Precision Filters for Single Use, Sterile Light-resistant Syringe with Needle for Single Use, Ultra-low Density Polyethylene Infusion Set for Single Use.**

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.: BJ19884031

Valid from: 2020-02-18
Valid until: 2024-05-26

Date, 2020-02-18

Christoph Dicks
Head of Certification/Notified Body

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

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Facility(ies):

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