

Declaration of Conformity

TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Manufacturer

Name MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.
Address 12th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan, 518055 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Product Information

Product Name Syringe Pump
Model/Specification MP-30, MP-30T, MP-30A
Basic UDI-DI 69268026MP3000000000001KB
Classification - Annex IX Class IIb, Rule 11
Conformity assessment Route Annex II Excluding 4

Notified Body

Name TÜV SÜD Product service GmbH
Address Ridlerstraße 65, D-80339 München, Germany
Identification number 0123
(EC) Certificate(s) G1 086916 0023 Rev.01
Confirmation Letter CL 086916 0056 Rev. 00

Authorised Representative

Name Shanghai International Holding Corp. GmbH
Address Eifflerstrasse 80, 20537 Hamburg, Germany

MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD. herewith declare that the above mentioned device(s) meet the transposition into national law, the provisions of Council Directive 93/42/EEC concerning medical devices; including, on March 21, 2010, the amendments by Council Directive 2007/47/EC. All supporting documentations are retained under the premises of the manufacturer.

We, as the manufacturer declare under our sole responsibility:

- for the above listed Directive Certificate the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and/or
- the above listed device(s) and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service.

Start of CE-Marking 2014-04
Place, Date of Issue Shenzhen, 2014-05-22
Signature, Date 
Name, Title Sun Yafei, Management Representative

Declaration of Conformity

TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Manufacturer

Name MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.
Address 12th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan, 518055 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Product Information

Product Name Infusion Pump
Model/Specification MP-60, MP-60A, MP-60T, MP-60C
Basic UDI-DI 69268026MP6000000000001P6
Classification - Annex IX Class IIb, Rule 11
Conformity assessment Route Annex II Excluding 4

Notified Body

Name TÜV SÜD Product service GmbH
Address Ridlerstraße 65, D-80339 München, Germany
Identification number 0123
(EC) Certificate(s) G1 086916 0023 Rev.01
Confirmation Letter CL 086916 0056 Rev. 00

Authorised Representative

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- for the above listed Directive Certificate the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and/or
- the above listed device(s) and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service.

Start of CE-Marking 2014-04
Place, Date of Issue Shenzhen, 2024-05-22
Signature, Date SA Y F
Name, Title Sun Yafei, Management Representative

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM CERTIFICATION

Certificate No.016XZ23Q30394R0M
Unified social credit code:91440300573106363N

This is to Certify that the Quality Management System of

MEDCAPTAIN MEDICAL TECHNOLOGY CO.,LTD

is in conformity with
GB/T19001-2016 idt ISO9001:2015 Standard, applies to

SYRINGE PUMPS, INFUSION PUMPS, INFUSION WORKSTATIONS, INFUSION CENTRAL
MONITORING SYSTEMS, DVT PREVENTIVE PUMPS, THROMBOELASTOGRAPH INSTRUMENTS
AND REAGENTS, VEIN ILLUMINATORS, ENTERAL FEEDING PUMPS, VIDEO LARYNGOSCOPES,
CHEMILUMINESCENCE IMMUNOASSAY ANALYZERS AND REAGENTS, HEMOSTASIS
REAGENTS, BLOOD GROUPING SYSTEM, SPIROMETERS, NUCLEIC ACID EXTRACTION
SYSTEMS, AND OXYGEN CONCENTRATORS (WITHIN THE SCOPE OF QUALIFICATION)
REGISTERED ADDRESS: 12TH FLOOR, BAIWANG RESEARCH BUILDING NO.5158 SHAHE WEST
ROAD XILI, NANSHAN 518055 SHENZHEN, GUANGDONG PEOPLE'S REPUBLIC OF CHINA
OPERATION ADDRESS: 12TH FLOOR, BAIWANG RESEARCH BUILDING NO.5158 SHAHE WEST
ROAD XILI, NANSHAN 518055 SHENZHEN, GUANGDONG PEOPLE'S REPUBLIC OF CHINA
(DISTRIBUTION); BUILDING 7, SHENZHEN INTERNATIONAL INNOVATION VALLEY, DASHI
ROAD 1, NANSHAN, SHENZHEN, GUANGDONG, PEOPLE'S REPUBLIC OF CHINA (DESIGN AND
DEVELOPMENT, AND DISTRIBUTION); BUILDING C, JIALE AND TECHNOLOGY INDUSTRIAL
PARK, MATIAN STREET, GUANGMING, SHENZHEN, GUANGDONG, PEOPLE'S REPUBLIC OF
CHINA (PRODUCTION)

Date of Initial Issuance: Mar. 3, 2023
Date of Expiration: Mar. 2, 2026

BCC Inc.
President:



BCC Address: Room 1101, Floor 11, Building 1, Guoyingyuan, Xicheng District, Beijing, P.R.C.
This certificate is valid within state - specified validities of administrative and qualification licensing.
The effectiveness of this certificate shall be maintained by regular surveillance audit,
the validity of the certificate can be inquired through www.bcc.com.cn or by QR code.
The information of this certificate available for inquiry on CNCA's website: www.cnca.gov.cn.



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C016-M



CERTIFICATE OF OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEM CERTIFICATION

Certificate No.016XZ23S30263R0M
Unified social credit code:91440300573106363N

This is to Certify that the Occupational Health and Safety Management System of

MEDCAPTAIN MEDICAL TECHNOLOGY CO.,LTD

is in conformity with
GB/T 45001-2020 idt ISO 45001:2018 Standard, applies to

SYRINGE PUMPS, INFUSION PUMPS, INFUSION WORKSTATIONS, INFUSION CENTRAL
MONITORING SYSTEMS, DVT PREVENTIVE PUMPS, THROMBOELASTOGRAPH INSTRUMENTS
AND REAGENTS, VEIN ILLUMINATORS, ENTERAL FEEDING PUMPS, VIDEO LARYNGOSCOPES,
CHEMILUMINESCENCE IMMUNOASSAY ANALYZERS AND REAGENTS, HEMOSTASIS
REAGENTS, BLOOD GROUPING SYSTEM, SPIROMETERS, NUCLEIC ACID EXTRACTION
SYSTEMS, AND OXYGEN CONCENTRATORS (WITHIN THE SCOPE OF QUALIFICATION)
REGISTERED ADDRESS: 12TH FLOOR, BAIWANG RESEARCH BUILDING NO.5158 SHAHE WEST
ROAD XILI, NANSHAN 518055 SHENZHEN, GUANGDONG PEOPLE'S REPUBLIC OF CHINA
OPERATION ADDRESS: 12TH FLOOR, BAIWANG RESEARCH BUILDING NO.5158 SHAHE WEST
ROAD XILI, NANSHAN 518055 SHENZHEN, GUANGDONG PEOPLE'S REPUBLIC OF CHINA
(DISTRIBUTION); BUILDING 7, SHENZHEN INTERNATIONAL INNOVATION VALLEY, DASHI
ROAD 1, NANSHAN, SHENZHEN, GUANGDONG, PEOPLE'S REPUBLIC OF CHINA (DESIGN AND
DEVELOPMENT, AND DISTRIBUTION); BUILDING C, JIALE AND TECHNOLOGY INDUSTRIAL
PARK, MATIAN STREET, GUANGMING, SHENZHEN, GUANGDONG, PEOPLE'S REPUBLIC OF
CHINA (PRODUCTION)

Date of Initial Issuance: Mar. 3, 2023
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President:



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This certificate is valid within state - specified validities of administrative and qualification licensing.
The effectiveness of this certificate shall be maintained by regular surveillance audit,
the validity of the certificate can be inquired through www.bcc.com.cn or by QR code.
The information of this certificate available for inquiry on CNCA's website: www.cnca.gov.cn.



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C016-M





Certificate

No. Q5 086916 0024 Rev. 05

Holder of Certificate: **MEDCAPTAIN MEDICAL
TECHNOLOGY CO., LTD.**
12th Floor, Baiwang Research Building
No.5158 Shahe West Road
Xili, Nanshan
518055 Shenzhen, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Syringe Pumps, Infusion Pumps, Infusion Workstations, Infusion Central Monitoring Systems, DVT Preventive Pumps, Infusion Docking Stations, Thromboelastograph Instruments and Reagents, Vein Illuminators, Enteral Feeding Pumps, Video Laryngoscopes, Chemiluminescence Immunoassay Analyzers and Reagents, Hemostasis Reagents, Colloidal Gold Reagents, Blood Grouping Systems, Spirometers, Nucleic Acid Extraction Systems, and Oxygen Concentrators.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 086916 0024 Rev. 05

Report No.: GZ2311701

Valid from: 2023-02-17

Valid until: 2026-02-16

Date, 2022-11-22

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 086916 0024 Rev. 05

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.
12th Floor, Baiwang Research Building, No.5158 Shahe West
Road, Xili, Nanshan, 518055 Shenzhen, Guangdong, PEOPLE'S
REPUBLIC OF CHINA

Distribution of Syringe Pumps, Infusion Pumps, Infusion
Workstations, Infusion Central Monitoring Systems, DVT
Preventive Pumps, Infusion Docking Stations,
Thromboelastograph Instruments and Reagents, Vein Illuminators,
Enteral Feeding Pumps, Video Laryngoscopes,
Chemiluminescence Immunoassay Analyzers and Reagents,
Hemostasis Reagents, Colloidal Gold Reagents, Blood Grouping
Systems, Spirometers, Nucleic Acid Extraction Systems, and
Oxygen Concentrators.

MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.
Building 7, Shenzhen International Innovation Valley, Dashi Road
1, Nanshan, 518055 Shenzhen, Guangdong, PEOPLE'S
REPUBLIC OF CHINA

Design and Development, and Distribution of Syringe Pumps,
Infusion Pumps, Infusion Workstations, Infusion Central Monitoring
Systems, DVT Preventive Pumps, Infusion Docking Stations,
Thromboelastograph Instruments and Reagents, Vein Illuminators,
Enteral Feeding Pumps, Video Laryngoscopes,
Chemiluminescence Immunoassay Analyzers and Reagents,
Hemostasis Reagents, Colloidal Gold Reagents, Blood Grouping
Systems, Spirometers, Nucleic Acid Extraction Systems, and
Oxygen Concentrators.

MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.
Building C, Jiale Science and Technology Industrial Park, Matian
Street, Guangming, 518106 Shenzhen, Guangdong, PEOPLE'S
REPUBLIC OF CHINA

Production of Syringe Pumps, Infusion Pumps, Infusion
Workstations, Infusion Central Monitoring Systems, DVT
Preventive Pumps, Infusion Docking Stations,
Thromboelastograph Instruments and Reagents, Vein Illuminators,
Enteral Feeding Pumps, Video Laryngoscopes,
Chemiluminescence Immunoassay Analyzers and Reagents,
Hemostasis Reagents, Colloidal Gold Reagents, Blood Grouping
Systems, Spirometers, Nucleic Acid Extraction Systems, and
Oxygen Concentrators.

-



**Add value.
Inspire trust.**

TÜV SÜD Product Service GmbH · Ridlerstr. 65 · 80339 Munich · Germany

MEDCAPTAIN MEDICAL
TECHNOLOGY CO., LTD.
12th Floor, Baiwang Research Building
No.5158 Shahe West Road
Xili, Nanshan
518055 SHENZHEN, GUANGDONG
PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
86916	713336204 713257146	medical_devices@tuvsud.com	N/A	2024-05-15	1 of 6

**TÜV SÜD Product Service GmbH
Confirmation Letter
CL 086916 0056 Rev. 00**

Reference: 713336204 | 713257146

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: [CN-MF-000005925](#)

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH
Certification body for medical Products
Ridlerstr. 65
80339 Munich
Germany

tuvsud.com/ps
Hotline: +49 89 50084-747





If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

For certificate validity see www.tuvsud.com/ps-cert?q=CL 086916 0056 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,

15th May 2024.

TÜV SÜD Product Service GmbH
Medical and Health Services

A handwritten signature in blue ink, appearing to read 'Ben Xu'.

Ben Xu
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

A handwritten signature in blue ink, appearing to read 'Tunde Junaid'.

Tunde Junaid
Application Reviewer



Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Syringe Pump 69268026MP3000000000001KB	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 086916 0023 Rev.01; NB0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Syringe Pump 69268026HP300000001NE	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 086916 0023 Rev.01; NB0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Syringe Pump 69268026SY500000000001MW	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 086916 0023 Rev.01; NB0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Infusion Pump 69268026MP6000000000001P6	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 086916 0023 Rev.01; NB0123 or ☐ Evidence that a competent authority of a Member State had



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Infusion Pump 69268026SYS601000000001PY	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 086916 0023 Rev.01; NB0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Infusion Pump 69268026SYS700000000001Q8	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 086916 0023 Rev.01; NB0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Infusion Workstation 69268026MP8000000000001RQ	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 086916 0023 Rev.01; NB0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Infusion Workstation 69268026HP8000000000001JD	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate G1 086916 0023 Rev.01; NB0123 or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	Individual Article number:	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Infusion Workstation 69268026HP80MRI00000001UU	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 086916 0023 Rev.01; NB0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Infusion Workstation 69268026MS1000000000001LS	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 086916 0023 Rev.01; NB0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
DVT Preventive Pump 69268026TP2000000000001UB	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 086916 0023 Rev.01; NB0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Enteral Feeding Pump 69268026EP6000000000001BE	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☒ N/A or	☒ Certification as follows: Certificate G1 086916 0023 Rev.01; NB0123 or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive: N/A

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024/05/15	713336204 713257146	Initial issue



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 086916 0023 Rev. 01

Manufacturer:

**MEDCAPTAIN MEDICAL
TECHNOLOGY CO., LTD.**

12th Floor, Baiwang Research Building
No.5158 Shahe West Road
Xili, Nanshan
518055 Shenzhen, Guangdong
PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies): Syringe Pump, Infusion Pump, Infusion
Workstation, DVT Preventive Pump, Enteral
Feeding Pump**

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10869160023Rev.01

Report No.: GZ2111701

Valid from: 2021-05-18

Valid until: 2024-05-26

Date, 2021-05-18

Christoph Dicks
Head of Certification/Notified Body