Product Service

CERTIFICATE

No. Q1N 17 07 89208 006

Holder of Certificate: **Qingdao Hiprove Medical Technologies Co., Ltd.**
ROOM 403, NO.592, TONGHE ROAD
266035 QINGDAO
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Qingdao Hiprove Medical Technologies Co., Ltd.
ROOM 403, NO.592, TONGHE ROAD, 266035
QINGDAO, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: Design and Development, Production and Distribution of Infusion Pump.

Applied Standard(s): EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

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). See also notes overleaf.

Report No.: BJ1785004

Valid from: 2017-09-09
Valid until: 2020-09-08

Date, 2017-08-25

Stefan Preiß

Page 1 of 1

DAkkS Deutsche Akkreditierungsstelle D-ZM-11521-01-00

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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DAkkS CRTZ / 10.13

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

认 证 证 书

证书号：Q1N 17 07 89208 006

证书持有者： 青岛海普乐医疗技术有限公司
青岛市市北区同和路592号403户
邮编：266035

生产场地： 青岛海普乐医疗技术有限公司
青岛市市北区同和路592号403户
邮编：266035

认证标志：

认证范围： 设计和开发、生产和分销：
输液泵。

认证标准： EN ISO 13485:2012 + AC:2012
医疗器械 - 质量管理体系 - 用于法规的要求
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

认证机构TÜV SÜD产品服务有限公司证明上述公司已经建立并运行了满足上述所列标准要求的质量体系。

报告号： BJ1785004

生效期： 2017-09-09
有效期： 2020-09-08

573981

发证日期： 2017-08-25

Stefan Preiß

第一页共一页

本证书是由具有法律效力的英文证书翻译而来

DAkkS Deutsche Akkreditierungsstelle D-ZM-11521-01-00

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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Product Service

CERTIFICATE

No. Q2N 17 07 89208 007

Holder of Certificate: **Qingdao Hiprove Medical Technologies Co., Ltd.**
ROOM 403, NO.592, TONGHE ROAD
266035 QINGDAO
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Qingdao Hiprove Medical Technologies Co., Ltd.
ROOM 403, NO.592, TONGHE ROAD, 266035
QINGDAO, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: Production and Distribution of
High Pressure Angiographic Syringes,
Disposable Sterilized Latex Surgical Gloves,
Disposable Syringe Sets, Infusion Sets,
Blood Transfusion Sets, Lap Sponges, Alcohol Swabs,
Urine Bags, Disposable Medical Latex Examination Gloves,
Gauze Sponges, Gauze Rolls, First Aid Kit, Bandages,
First Aid Bandages.

Applied Standard(s): EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ1785004

Valid from: 2017-09-09
Valid until: 2020-09-08

Date, 2017-08-25

Stefan Preiß

Page 1 of 1

DAkkS Deutsche Akkreditierungsstelle D-ZM-13321-01-00

DAkkS CRT2 / 10.13

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證証書 ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

认 证 证 书

证书号：Q2N 17 07 89208 007

证书持有者： 青岛海普乐医疗技术有限公司
青岛市市北区同和路592号403户
邮编：266035

生产场地： 青岛海普乐医疗技术有限公司
青岛市市北区同和路592号403户
邮编：266035

认证标志：

认证范围： 生产和分销：
高压造影注射器、一次性灭菌乳胶手术手套、一次性注射器、输液器、输血器、腹部垫、酒精擦片、尿袋、一次性医用乳胶检查手套、纱布、纱布卷、急救包、绷带、急救绷带。

认证标准： **EN ISO 13485:2012 + AC:2012**
医疗器械 - 质量管理体系 - 用于法规的要求
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

认证机构TÜV SÜD产品服务有限公司证明上述公司已经建立并运行了满足上述所列标准要求的质量体系（删除第7.3条款）。

报告号： BJ1785004

生效期： 2017-09-09
有效期： 2020-09-08

发证日期： 2017-08-25

Stefan Preiß

573980

第一页共一页
本证书是由具有法律效力的英文证书翻译而来

DAkkS Deutsche Akkreditierungsstelle D-ZM-13321-01-00

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q2N 17 07 89208 007

Holder of Certificate: **Qingdao Hiprove Medical Technologies Co., Ltd.**
ROOM 403, NO.592, TONGHE ROAD
266035 QINGDAO
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
Qingdao Hiprove Medical Technologies Co., Ltd.
ROOM 403, NO.592, TONGHE ROAD, 266035
QINGDAO, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate:
Production and Distribution of High Pressure Angiographic Syringes, Disposable Sterilized Latex Surgical Gloves, Disposable Syringe Sets, Infusion Sets, Blood Transfusion Sets, Lap Sponges, Alcohol Swabs, Urine Bags, Disposable Medical Latex Examination Gloves, Gauze Sponges, Gauze Rolls, First Aid Kit, Bandages, First Aid Bandages.

Applied Standard(s):
EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ1785004

Valid from: 2017-09-09
Valid until: 2020-09-08

Date, 2017-08-25

Stefan Preiß

Page 1 of 1

DAkkS Deutsche Akkreditierungsstelle D-ZM-11323-01-00

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 17 07 89208 006

Holder of Certificate: **Qingdao Hiprove Medical Technologies Co., Ltd.**
ROOM 403, NO.592, TONGHE ROAD
266035 QINGDAO
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Qingdao Hiprove Medical Technologies Co., Ltd.
ROOM 403, NO.592, TONGHE ROAD, 266035
QINGDAO, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Infusion Pump.**

Applied Standard(s): EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

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). See also notes overleaf.

Report No.: BJ1785004

Valid from: 2017-09-09
Valid until: 2020-09-08

Date, 2017-08-25

Stefan Preiß

Page 1 of 1

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q2N 14 07 89208 002

Holder of Certificate: **Qingdao Hiprove Medical Technologies Co., Ltd.**
ROOM 403, NO.592, TONGHE ROAD
266035 QINGDAO
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Qingdao Hiprove Medical Technologies Co., Ltd.
ROOM 403, NO.592, TONGHE ROAD, 266035 QINGDAO,
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Production and Distribution of High Pressure Angiographic Syringes, Disposable Sterilized Latex Surgical Gloves, Disposable Syringe Sets, Infusion Sets, Blood Transfusion Sets, Lap Sponges, Alcohol Swabs, Urine Bags, Disposable Medical Latex Examination Gloves, Gauze Sponges, Gauze Rolls, First Aid Kit, Bandages, First Aid Bandages.**

Applied Standard(s): EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ1485001

Valid from: 2014-09-09
Valid until: 2017-09-08

572726

Date, 2014-09-11

Hans-Heiner Junker

Page 1 of 1

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 14 07 89208 001

Holder of Certificate: **Qingdao Hiprove Medical Technologies Co., Ltd.**
ROOM 403, NO.592, TONGHE ROAD
266035 QINGDAO
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Qingdao Hiprove Medical Technologies Co., Ltd.
ROOM 403, NO.592, TONGHE ROAD, 266035 QINGDAO,
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Infusion Pump.**

Applied Standard(s): EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

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). See also notes overleaf.

Report No.: BJ1485001

Valid from: 2014-09-09
Valid until: 2017-09-08

572729

Date, 2014-09-10

Hans-Heiner Junker

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 14 08 89208 004

Manufacturer:
Qingdao Hiprove Medical Technologies Co., Ltd.
ROOM 403, NO.592, TONGHE ROAD
266035 QINGDAO
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:
HAP Electronics GmbH
Friedrichstr. 73D,
40217 Dusseldorf
GERMANY

Product Category(ies):
High Pressure Angiographic Syringes, Disposable Sterilized Latex Surgical Gloves, Disposable Syringe Sets, Infusion Sets, Blood Transfusion Sets, Lap Sponges.

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

Report No.: BJ1485001

Valid from: 2014-09-09
Valid until: 2019-09-08

572722

Date, 2014-09-11

Hans-Heiner Junker

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

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)
No. G2 14 08 89208 004

Facility(ies):
Qingdao Hiprove Medical Technologies Co., Ltd.
ROOM 403, NO.592, TONGHE ROAD, 266035 QINGDAO,
PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 14 08 89208 005

Manufacturer: **Qingdao Hiprove Medical Technologies Co., Ltd.**
ROOM 403, NO.592, TONGHE ROAD
266035 QINGDAO
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **HAP Electronics GmbH**
Friedrichstr. 73D,
40217 Dusseldorf
GERMANY

Product Category(ies): **Alcohol Swabs, Urine Bags, Disposable Medical Latex Examination Gloves, Gauze Sponges, Gauze Rolls, First Aid Kit, Bandages, First Aid Bandages.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: BJ1485001

Valid from: 2014-09-09
Valid until: 2019-09-08

Date, 2014-09-11

Hans-Helmer Junker

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

Product Service

EC Certificate
Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)
No. G2S 14 08 89208 005

Facility(ies): Qingdao Hiprove Medical Technologies Co., Ltd.
ROOM 403, NO.592, TONGHE ROAD, 266035 QINGDAO,
PEOPLE'S REPUBLIC OF CHINA

ZERTIFIKAT ◆ CERTIFICADO ◆ CERTIFICAT ◆ 認証書 ◆ СЕРТИФИКАТ

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 14 07 89208 003

Manufacturer: **Qingdao Hiprove Medical Technologies Co., Ltd.**
ROOM 403, NO.592, TONGHE ROAD
266035 QINGDAO
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **HAP Electronics GmbH**
Friedrichstr. 73D,
40217 Dusseldorf
GERMANY

Product Category(ies): **Infusion 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. See also notes overleaf.

Report No.: BJ1485001

Valid from: 2014-09-09
Valid until: 2019-09-08

572724

Date, 2014-09-11

Hans-Heiner Junker

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

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A1 / 04.11

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ

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 14 07 89208 003

Facility(ies): Qingdao Hiprove Medical Technologies Co., Ltd.
ROOM 403, NO.592, TONGHE ROAD, 266035 QINGDAO,
PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 14 07 89208 003

Manufacturer:
Qingdao Hiprove Medical Technologies Co., Ltd.
ROOM 403, NO.592, TONGHE ROAD
266035 QINGDAO
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:
HAP Electronics GmbH
Friedrichstr. 73D,
40217 Dusseldorf
GERMANY

Product Category(ies):
Infusion 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. See also notes overleaf.

Report No.: BJ1485001

Valid from: 2014-09-09
Valid until: 2019-09-08

572725

Date, 2014-09-11

Hans-Heiner Junker

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

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 14 08 89208 005

Manufacturer:
Qingdao Hiprove Medical Technologies Co., Ltd.
ROOM 403, NO.592, TONGHE ROAD
266035 QINGDAO
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:
HAP Electronics GmbH
Friedrichstr. 73D,
40217 Dusseldorf
GERMANY

Product Category(ies):
Alcohol Swabs, Urine Bags, Disposable Medical Latex Examination Gloves, Gauze Sponges, Gauze Rolls, First Aid Kit, Bandages, First Aid Bandages.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: BJ1485001

Valid from: 2014-09-09
Valid until: 2019-09-08

TÜV SÜD 572721

Date, 2014-09-11

Hans-Heiner Junker

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 14 08 89208 004

Manufacturer:

Qingdao Hiprove Medical Technologies Co., Ltd.
ROOM 403, NO.592, TONGHE ROAD
266035 QINGDAO
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

HAP Electronics GmbH
Friedrichstr. 73D,
40217 Dusseldorf
GERMANY

Product Category(ies):

High Pressure Angiographic Syringes, Disposable Sterilized Latex Surgical Gloves, Disposable Syringe Sets, Infusion Sets, Blood Transfusion Sets, Lap Sponges.

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

Report No.: BJ1485001

Valid from: 2014-09-09
Valid until: 2019-09-08

572723

Date, 2014-09-11

Hans-Heiner Junker

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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