



质量管理体系认证证书

兹 证 明

上海达华医疗器械有限公司

统一社会信用代码: 91310230134430145R

中国 上海崇明工业园区崐山路 85 号 202150

建立和实施的管理体系符合:

YY/T0287-2017/ISO 13485:2016

体系覆盖范围:

一次性使用输血器、一次性使用离心式血浆分离器、一次性使用血液透析管路、一次性使用血小板分离器（仅供出口）、单采血浆机、女用避孕套及其润滑剂（以上产品按医疗器械注册证范围）、引流袋（按医疗器械备案凭证范围）的设计、生产。

审核地点: 上海市崇明区崇明工业园区崐山路85号4幢B区、5幢A区

本证书注册编号: SAC20Y10007R1M

证书有效期: 2020年12月02日至2023年12月01日

本证书的有效性依据年度监督审核获得保持

认证机构



2020年12月02日

上海质量体系审核中心

中国 上海市武夷路 258 号 <http://www.sac.org.cn>

本证书信息可在国家认证认可监督管理委员会官方网站 (www.cnca.gov.cn) 上查询



QUALITY MANAGEMENT SYSTEM CERTIFICATE OF CONFORMITY

Shanghai Dahua Medical Apparatus Co., Ltd.

Unified Social Credit Code: 91310230134430145R

No.85 Shengshan Road, Chongming Industrial Park, Shanghai 202150, China

has established and applied a quality management system in conformity with
YY/T0287-2017/ISO 13485:2016

The scope covered by the system is:

design, production for disposable blood transfusion sets, disposable centrifugal plasma separator systems, disposable Hemo-dialysis tubing sets, disposable platelet apheresis systems (export only), plasma collection machine, woman's condom and lubricant (above products shall be limited in its qualification certificate), drainage bags (shall be limited in its qualification certificate).

Audit Address: Zone B of Building 4, Zone A of Building 5, No.85 Shengshan Road, Chongming Industrial Park, Chongming District, Shanghai

Certificate Registration: SAC20Y10007R1M

Duration of Validity: 2020.12.02—2023.12.01

The validity of this certificate will be maintained through annual surveillance audit.



Tanfang

Certification Body

Date Dec.02, 2020

Shanghai Audit Center of Quality System

No.258 Wuyi Road, Shanghai P.R. China <http://www.sac.org.cn>

This certificate information can be found at the official website (www.cnca.gov.cn) of Certification and Accreditation Administration of the People's Republic of China (CNCA).



质量管理体系认证证书

上海达华医疗器械有限公司

统一社会信用代码: 91310230134430145R

中国 上海崇明工业园区崂山路 85 号 202150

建立和实施的管理体系符合:

GB/T 19001-2016/ISO 9001:2015

体系覆盖范围:

一次性使用输血器、一次性使用离心式血浆分离器、一次性使用血液透析管路、一次性使用血小板分离器(仅供出口)、单采血浆机、女用避孕套及其润滑剂(以上产品按医疗器械注册证范围)、引流袋(按医疗器械备案凭证范围)的设计、生产。

审核地点: 上海市崇明区崇明工业园区崂山路 85 号 4 幢 B 区、5 幢 A 区

本证书注册编号: 00320Q30395R1M

证书有效期: 2020 年 12 月 02 日至 2023 年 12 月 01 日

本证书的有效性依据年度监督审核获得保持

蒋平



认证机构

2020 年 12 月 02 日



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C003-M

上海质量体系审核中心

中国 上海 武夷路258号 <http://www.sac.org.cn>

本证书信息可在国家认证认可监督管理委员会官方网站 (www.cnca.gov.cn) 上查询



QUALITY MANAGEMENT SYSTEM CERTIFICATE OF CONFORMITY

Shanghai Dahua Medical Apparatus Co., Ltd.

Unified Social Credit Code: 91310230134430145R

No.85 Shengshan Road, Chongming Industrial Park, Shanghai 202150, China

has established and applied a quality management system in conformity with

GB/T 19001-2016/ISO 9001:2015

The scope covered by the system is:

design, production for disposable blood transfusion sets, disposable centrifugal plasma separator systems, disposable Hemo-dialysis tubing sets, disposable platelet apheresis systems (export only), plasma collection machine, woman's condom and lubricant (above products shall be limited in its qualification certificate), drainage bags (shall be limited in its qualification certificate).

Audit Address: Zone B of Building 4, Zone A of Building 5, No.85 Shengshan Road, Chongming Industrial Park, Chongming District, Shanghai

Certificate Registration: 00320Q30395R1M

Duration of Validity: 2020.12.02—2023.12.01

The validity of this certificate will be maintained through annual surveillance audit.

Certification Body



Date Dec.02, 2020



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C003-M

Shanghai Audit Center of Quality System

No.258 Wuyi Road, Shanghai P.R.China <http://www.sac.org.cn>

This certificate information can be found at the official website (www.cnca.gov.cn) of Certification and Accreditation Administration of the People's Republic of China (CNCA)



QUALITY MANAGEMENT SYSTEM CERTIFICATION OF CONFORMITY

Shanghai Dahua Medical Apparatus Co., Ltd.

Unified Social Credit Code: 91310230134430145R
No. 85 Shengshan Road, Chongming Industrial Park, Shanghai 202150, China

has established and applied a quality management system in conformity with
ISO 9001:2015

The scope covered by the system is:

design, production for disposable blood transfusion sets, disposable centrifugal plasma separator systems, disposable Hemo-dialysis tubing sets, disposable platelet apheresis systems (export only), plasma collection machine, woman's condom and lubricant (above products shall be limited in its qualification certificate), drainage bags (shall be limited in its qualification certificate).

Audit Address: Zone B of Building 4, Zone A of Building 5, No.85 Shengshan Road, Chongming Industrial Park, Chongming District, Shanghai

Certificate Registration: ANAB20Q3037791/1

Duration of Validity: 2020.12.02—2023.12.01

The validity of this certificate will be maintained through annual surveillance audit.

Certification Body



Date Dec.02, 2020



Shanghai Audit Center of Quality System

No.258 Wuyi Road, Shanghai P.R.China <http://www.sac.org.cn>

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