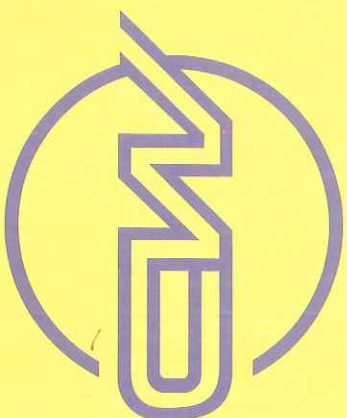




证书编号: 047200Q10047R3M

质量管理体系认证证书

兹证明

苏州优贝特医疗器械有限公司

(统一社会信用代码: 913205827573176918)

住所: 张家港市锦丰镇

生产地址: 张家港市锦丰镇

质量管理体系符合:

GB/T 19001-2016 idt ISO 9001:2015

体系覆盖:

脊柱固定器、金属股骨颈固定钉、金属接骨板(加压和保护性接骨板)、加压和保护性金属接骨板、脊柱前路固定板、锁定型金属接骨板、金属解剖型接骨板、金属带锁髓内钉、角度型接骨板、解剖型金属接骨板、金属接骨螺钉、空心钉安装器械包、脊柱固定器安装器械包、上肢接骨板安装器械包、下肢接骨板安装器械包、上肢锁定接骨板安装器械包、胫骨带锁髓内钉安装器械包、股骨带锁髓内钉安装器械包、金属带锁髓内钉安装器械包、下肢锁定接骨板安装器械包、骨牵引针的设计开发、生产和服务。

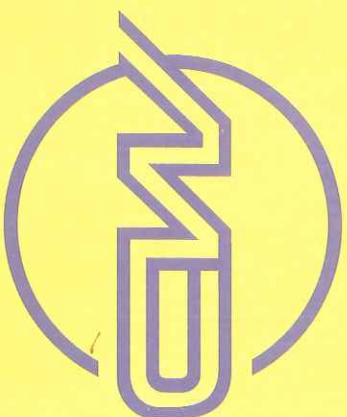
颁证日期: 2020 年 01 月 20 日
有效期至: 2023 年 01 月 19 日

总经理:

北京国医械华光认证有限公司



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C047-M



REGISTRATION NO. 04720Q10047R3M

CERTIFICATE

OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of

Suzhou Youbetter Medical Apparatus Co., Ltd.

Registered Address: Jinfeng Town, Zhangjiagang, Jiangsu Province, China
Manufacturing Address: Jinfeng Town, Zhangjiagang, Jiangsu Province, China

Has been assessed and conformed to the following standard(s)

GB/T 19001-2016 idt ISO 9001:2015

The certificate is valid for the following scope:

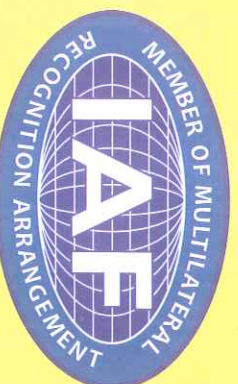
The Design, Development, Production and Service of products including spine fixation, metal compression cannulated screw, metal bone plate (compression and protective plate), compression and protective metal bone plate, anterior spine fixation plate, locking metal bone plate, metal anatomic plate, metal interlocking nail, angel bone plate, anatomic metal bone plate, metal bone screw, cannulated screw instrument set, spine fixation instrument set, upper limb bone plate instrument set, lower limb bone plate instrument set, upper limb locking bone plate instrument set, tibial interlocking nail instrument set, femoral interlocking nail instrument set, metal interlocking nail instrument set, lower limb locking bone plate instrument set, bone wire.

Date of issue: January 20, 2020

Date of expiry: January 19, 2023

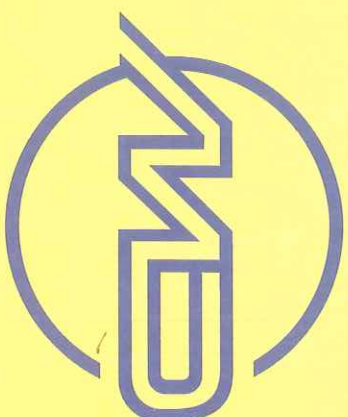
General Manager:

BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C047-M

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No. jia88, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993



证书编号: 04720Q10000056

医疗器械

质量管理体系认证证书

兹证明

苏州优贝特医疗器械有限公司

(统一社会信用代码: 913205827573176918)

住所: 张家港市锦丰镇

生产地址: 张家港市锦丰镇

质量管理体系符合:

YY/T 0287-2017 idt ISO 13485:2016

体系覆盖:

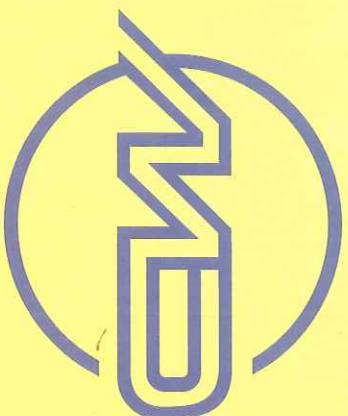
脊柱固定器、金属股骨颈固定钉、金属接骨板(加压和保护性接骨板)、加压和保护性金属接骨板、脊柱前路固定板、锁定型金属接骨板、金属解剖型接骨板、金属带锁髓内钉、角度型接骨板、解剖型金属接骨板、金属接骨螺钉、空心钉安装器械包、脊柱固定器安装器械包、上肢接骨板安装器械包、下肢接骨板安装器械包、上肢锁定接骨板安装器械包、胫骨带锁髓内钉安装器械包、股骨带锁髓内钉安装器械包、金属带锁髓内钉安装器械包、下肢锁定接骨板安装器械包、骨牵引针的设计开发、生产和销售。

颁证日期: 2020 年 01 月 20 日
有效期至: 2023 年 01 月 19 日

总经理:

北京国医械华光认证有限公司





REGISTRATION NO. 04720Q10000056

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Suzhou Youbetter Medical Apparatus Co., Ltd.

Registered Address: Jinfeng Town, Zhangjiagang, Jiangsu Province, China

Manufacturing Address: Jinfeng Town, Zhangjiagang, Jiangsu Province, China

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The Design, Development, Production and Service of products including spine fixation, metal compression cannulated screw, metal bone plate (compression and protective plate), compression and protective metal bone plate, anterior spine fixation plate, locking metal bone plate, metal anatomic plate, metal interlocking nail, angel bone plate, anatomic metal bone plate, metal bone screw, cannulated screw instrument set, spine fixation instrument set, upper limb bone plate instrument set, lower limb bone plate instrument set, upper limb locking bone plate instrument set, tibial interlocking nail instrument set, femoral interlocking nail instrument set, metal interlocking nail instrument set, lower limb locking bone plate instrument set, bone wire.

Date of issue: January 20,2020

Date of expiry: January 19,2023

General Manager:

BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (www.cmd.com.cn). Address: 5th floor of Zhong Lian building, No. jia88, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993