



山东国鉴认证有限公司

环境管理体系认证证书

NO: 174E220019R0S

兹 证 明

山东奥健颐医疗科技有限公司

山东省淄博市高新区民祥北路华鸿文化物流园四期7号楼二层西区南侧

统一社会信用代码: 91370303MA3RHQJ28P

环境管理体系符合标准:

GB/T 24001-2016/ISO 14001:2015

该环境管理体系适合:

一类医疗器械(定位膜、低温热塑板、医用高分子夹板)的生产和销售及相关管理活动

(上述范围若涉及行政许可前置审批、强制性认证, 本证书仅涵盖许可资质、证书范围内的产品及服务)



扫描二维码
验证证书有效性

颁证日期: 2022年01月19日

本证书有效期自2022年01月19日始至2025年01月18日

获证组织必须定期接受监督审核并经审核合格此证书方继续有效



中国认可
国际互认
管理体系

MANAGEMENT SYSTEM
CNAS C169-M

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山东省济南市市中区舜耕路217号九城尚都办公楼801 (250002) 山东国鉴认证有限公司



SHANDONG GUOJIAN CERTIFICATION CO.,LTD.

ENVIRONMENTAL MANAGEMENT SYSTEM CERTIFICATE

No:174E220019R0S

This is to certify that the Environmental Management system of

SHANDONG AOJIANYI MEDICAL TECHNOLOGY CO.,LTD.

SOUTH SIDE OF WEST ZONE,2F,BUILDING 7,PHASE IV,HUAHONG CULTURAL LOGISTICS PARK,
MINXIANG NORTH ROAD,HIGH TECH ZONE,ZIBO CITY,SHANDONG PROVINCE

Unified Social Credit Code:91370303MA3RHQJ28P

Environmental Management System

Has been awarded this certificate for compliance with the standard

GB/T 24001-2016/ISO 14001:2015

This Environmental Management System is valid for the

**THE RELATIVE MANAGEMENT ACTIVITIES OF PRODUCTION
AND SALE OF CLASS I MEDICAL DEVICES (POSITIONING MASK,
LOW-TEMPERATURE THERMOPLASTIC SHEET AND MEDICAL POLYMER SPLINT)**

(If the above scope involves pre-approval of administration permission and compulsory certification, this certificate only covers products/ services in the approved / certified scope.)



Date of issue:2022-01-19

Term of validity of this certificate:from 2022-01-19 to 2025-01-18

This certificate remains valid only if the certified organization accepts and passes regular surveillance audits

Scan the QR code to check
the validity of the certificate



中国认可
国际互认
管理体系

**MANAGEMENT SYSTEM
CNAS C169-M**

The validity of this certificate could be confirmed via official Website Of CNCA (www.cnca.gov.cn) Or the Website Of Certification Body (www.ccsge.cc). or contact 0531-67618299
ROOM 801, JIUCHENGSHANGDUBUILDING, NO.217CENTRAL SHUNGENG ROAD, JI'NAN CITY, SHANDONG PROVINCE, CHINA (250002)
SHANDONG GUOJIAN CERTIFICATION CO., LTD.



山东国鉴认证有限公司

质量管理体系认证证书

NO: 174Q220032R0S

兹 证 明

山东奥健颐医疗科技有限公司

山东省淄博市高新区民祥北路华鸿文化物流园四期7号楼二层西区南侧

统一社会信用代码: 91370303MA3RHQJ28P

质量管理体系符合标准:

GB/T 19001-2016/ISO 9001:2015

该质量管理体系适合:

一类医疗器械(定位膜、低温热塑板、医用高分子夹板)的生产和销售

(上述范围若涉及行政许可前置审批、强制性认证,本证书仅涵盖许可资质、证书范围内的产品及服务)

颁证日期: 2022年01月19日

本证书有效期自2022年01月19日始至2025年01月18日

获证组织必须定期接受监督审核并经审核合格此证书方继续有效



扫描二维码
验证证书有效性



张行明

公司代表(签名)

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)或认证机构网站(www.ccsge.cc)上查询,或致电0531-67618299

山东省济南市市中区舜耕路217号九城尚都办公楼801(250002)山东国鉴认证有限公司



SHANDONG GUOJIAN CERTIFICATION CO.,LTD.

QUALITY MANAGEMENT SYSTEM CERTIFICATION

No:174Q220032R0S

This is to certify that the quality system of

SHANDONG AOJIAN YI MEDICAL TECHNOLOGY CO.,LTD.

SOUTH SIDE OF WEST ZONE,2F,BUILDING 7,PHASE IV,HUAHONG CULTURAL LOGISTICS PARK,
MINXIANG NORTH ROAD,HIGH TECH ZONE,ZIBO CITY,SHANDONG PROVINCE

Unified Social Credit Code: 91370303MA3RHQJ28P

Quality Management System

Has been awarded this certificate for compliance with the standard

GB/T 19001-2016/ISO 9001:2015

This Quality Management System is valid for the

PRODUCTION AND SALE OF CLASS I MEDICAL DEVICES (POSITIONING MASK, LOW-TEMPERATURE THERMOPLASTIC SHEET AND MEDICAL POLYMER SPLINT)

(If the above scope involves pre-approval of administration permission and compulsory certification, this certificate only covers products/ services in the approved / certified scope.)



Date of issue: 2022-01-19

Term of validity of this certificate: from 2022-01-19 to 2025-01-18

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张行明

Representative of The Company

The validity of this certificate could be confirmed via official Website Of CNCA (www.cnca.gov.cn) Or the Website Of Certification Body (www.ccsqc.cc). or contact 0531-67618299
ROOM 801, JIUCHENGSHANGDUBUILDING, NO.217CENTRAL SHUNGENG ROAD, JI'NAN CITY, SHANDONG PROVINCE, CHINA (250002)
SHANDONG GUOJIAN CERTIFICATION CO., LTD.

Documentation Review



No. 0P211210.SAMCW77

Holder: Shandong Aojianyi Medical Technology Co., Ltd.
Huahong Cultural Logistics Park, North Minxiang Road, Zibo High-Tech Zone, Shandong Province, China.

Review goal: Verification of the presence of Technical Documentation compatible with the Medical Devices Regulation 2017/745 Annex I

Product: Thermoplastic Sheet (Radiotherapy Mask)

Model(s): (see the following annex)

Classification: Class I (Not Sterile according to the Manufacturer's declaration – therefore not requiring NB intervention.)

Review output: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices. Technical documentation identified with the no. TSTCF1206-MDR. The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Date of issue 10 December 2021

Expiry date 09 December 2026

Approver
ECM Service Director
Luca Redonni



Technical Expert
Amanda Payne



Ente Certificazione Macchine

Via Cà Bella, 243 - 40053 Valsamoggia Loc. Castello di Serravalle (Bo) Italy
☎ +39.0516705141 📠 +39.0516705156 ✉ info@entecerma.it 🌐 www.entecerma.it

Annex I

No. 0P211210.SAMCW77

Model(s):

AJY-KB, AJY-PB, AJY-FB, AJY-S01, AJY-S02, AJY-S03, AJY-S04, AJY-S05, AJY-S06, AJY-S07, AJY-S08, AJY-S09, AJY-S10, AJY-S11, AJY-S12, AJY-T13, AJY-T14, AJY-T15, AJY-T16, AJY-X01L, AJY-X01M, AJY-X01S, AJY-X02L, AJY-X02S, AJY-X03L, AJY-X03M, AJY-X03S, AJY-B01L, AJY-B01S, AJY-B02L, AJY-B02M, AJY-B02S, AJY-B03L, AJY-B03M, AJY-B03S, AJY-B05L, AJY-B05M, AJY-B05S, A-M01, A-M01-01, A-M01-02, A-M01-D01, A-M02, A-M02-01, A-M02-02, A-M02-D01, A-M03, A-M04L, A-M04S, A-M04-D01, A-J01, A-J02, A-J03, A-J04, A-X01, A-T01, A-T02, A-T03, A-T04, A-T05



Report Number: QIP-ASI215475

Audit Date : 10 Apr.,2021

This report is issued by Focus Technology Co., Ltd. (Made-in-China.com) and the supervising inspectorate (SGS-CSTC Standards Technical Services Co., Ltd.) to confirm that:

Company Name : SHANDONG AOJIAN YI MEDICAL TECHNOLOGY CO., LTD.
山东奥健颐医疗科技有限公司

Showroom : <https://aojianyisplint.en.made-in-china.com>

Address : South Side of West District, Floor 2, Building 7, Phase 4, Huahong Cultural Logistics Park, Minxiang North Road, High Tech Zone, Zibo, Shandong, China

Product : Thermoplastic Orthopedic Splinting Material, Thermoplastic Nasal Splint, Radiotherapy Mask, Thermoplastic Splint, External Nasal Splint, Aluminum Nasal Splint, Finger Splint, Wrist Splint, Hand Splint, Thermoplastic Scoliosis Brace, Thermoplastic Leg Splint

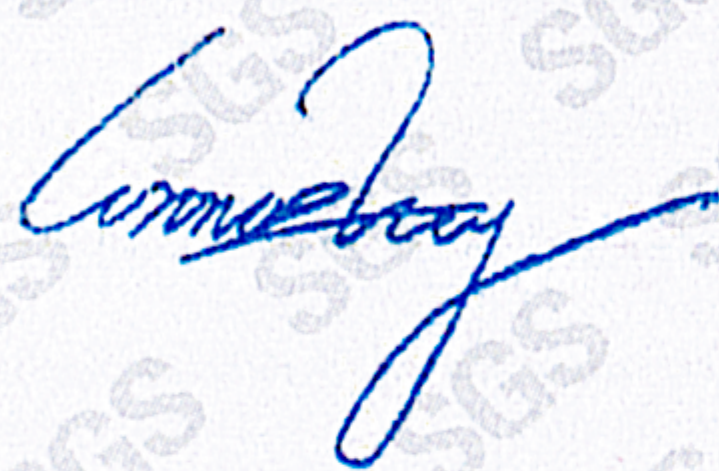
has been on site audited for the Following Scope of Activity

1. General Information
2. Foreign Trade Capacity
3. Product Research & Development Capacity
4. Management System and Product Certification
5. Production Capacity & Quality Control
6. Working Environment
7. Energy Saving and Emission Reduction
8. Photos



General Comments:

SHANDONG AOJIAN YI MEDICAL TECHNOLOGY CO., LTD. is a manufacturer with 11 employees; it was established in 2020, located in South Side of West District, Floor 2, Building 7, Phase 4, Huahong Cultural Logistics Park, Minxiang North Road, High Tech Zone, Zibo, Shandong, China. The workshops occupy an area of 900 square meters. They have passed ISO9001, ISO14001 management system certificates.



Sign for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd.

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