DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-YH-06.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

Manufacturer

Name: XINYANG YIHE NON-WOVEN CO., LTD.
Address: XIXIAN INDUSTRIAL PARK, XINYANG CITY, HENAN PROVINCE, CHINA

Product Information

Name: Patient Suit
Model: S, M, L, XL, XXL, XXXL
GMDN: 35092
Basic UDI-DI: /
Classification: Class I

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: 刘树青 Date: 2021.2.12

Position: GM Place: HeNan

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 14126: 2003

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-YH-03.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

Manufacturer

Name: XINYANG YIHE NON-WOVEN CO., LTD.
Address: XIXIAN INDUSTRIAL PARK, XINYANG CITY, HENAN PROVINCE, CHINA

Product Information

Name: Coverall
Model: S, M, L, XL, XXL, XXXL, XXXXL, XXXXXL
GMDN: 58390
Basic UDI-DI: /
Classification: Class I

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: 刘树青 Date: 2021.2.12

Position: GM Place: HeNan

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-YH-04.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

Manufacturer

Name: XINYANG YIHE NON-WOVEN CO., LTD.
Address: XIXIAN INDUSTRIAL PARK, XINYANG CITY, HENAN PROVINCE, CHINA

Product Information

Name: Isolation Gown
Model: S, M, L, XL, XXL, XXXL, XXXXL
GMDN: 35492
Basic UDI-DI: /
Classification: Class I

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: 刘树青 Date: 2021.2.12

Position: GM Place: HeNan

File No: CE/MDR-YH-01-02 Ver: A

Declaration of Conformity

Regarding Medical Device Regulation(2017/745)

Manufacturer
Name: XINYANG YIHE NON-WOVEN CO., LTD
Address: XIXIAN INDUSTRIAL PARK, XINYANG CITY, HENAN PROVINCE, CHINA

European Authorised Representative
Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product
Name: Face mask
Model: 17.5cm×9.5cm
SRN: -
UDI-DI: -

Classification: I
Rule: According to Rule 1, Annex VIII, EU Medical Device Regulation (2017/745)

Conformity assessment procedure: Annex II+III

We confirm our product meets the requirements of Regulation (EU) 2017/745 and the following harmonized standards.

EN ISO 14971: 2012
EN ISO 15223-1: 2016
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 1041: 2008
EN 14683:2019

Signature: 刘树青

Date: 2020.4.28

Position: General Manager

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo

Authorized Signature (S)

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Manufacturer

Name: XINYANG YIHE NON-WOVEN CO., LTD.
Address: XIXIAN INDUSTRIAL PARK, XINYANG CITY, HENAN PROVINCE, CHINA

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-YH-05.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Product Information

Name: Lab Coat
Model: S, M, L, XL, XXL
GMDN: 32170
Basic UDI-DI: /
Classification: Class I

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: 刘树青 Date: 2021.2.12

Position: GM Place: HeNan

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sunga

Authorized Signature (S)

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Manufacturer

Name: XINYANG YIHE NON-WOVEN CO., LTD.
Address: XIXIAN INDUSTRIAL PARK, XINYANG CITY, HENAN PROVINCE, CHINA

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 13795-1:2019

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-YH-02.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Product Information

Name: Surgical Gown
Model: S, M, L, XL, XXL, XXXL, XXXXL
GMDN: 35091
Basic UDI-DI: /
Classification: Class I

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: 刘树青 Date: 2021.2.12

Position: GM Place: HeNan

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo Global Service

Authorized Signature (S)

医疗器械生产许可证

许可证编号：豫药监械生产许20200156号

企业名称：信阳颐和非织布有限责任公司

生产地址：河南省信阳市息县工业集聚区

法定代表人：刘树青

生产范围：原分类目录：II类：6864医用卫生材料及敷料※；新分类目录：14-14：医护人员防护用品※※

企业负责人：刘树青

住　　所：河南省信阳市息县工业集聚区

发证部门：河南省药品监督管理局

有效期限：至　2026　年09　月13　日

发证日期：　2021　年09　月14　日

国家药品监督管理局制

国家药品监督管理局
National Medical Products Administration

中 EN

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网站首页>> 数据查询>> 医疗器械生产企业（许可）

国产和进口药品本位码查询说明 >> 数据查询使用说明 >>

- 产品抽检
- 药　品
- 医疗器械
  - 国产医疗器械产品（注册）
  - 国产器械（历史数据）
  - 国产医疗器械产品（备案）
  - 进口医疗器械产品（注册）
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快速查询

医疗器械

医疗器械生产企业（许可）

查询

高级查询

许可证编号

企业名称 查询

医疗器械生产企业（许可） 返回

许可证编号	豫药监械生产许20200156号
企业名称	信阳颐和非织布有限责任公司
法定代表人	刘树青
企业负责人	刘树青
住所	河南省信阳市息县工业集聚区
生产地址	河南省信阳市息县工业集聚区
生产范围	Ⅱ类：6864医用卫生材料及敷料;14-14:医护人员防护用品
发证部门	河南省药品监督管理局
发证日期	2020-06-02
有效期限	2021-06-01
生产产品登记表	生产产品登记表
注	企业如对数据有疑问，请咨询国家局信息中心，电话010-88332877，88331520（工作日），也可通过发邮件与我们联系：邮件地址yaopinshuju@nmpaic.org.cn，邮件主题请注明“医疗器械生产企业（许可）-数据（许可证号/备案号）数据问题”。数据来源于省局，由省局通过数据共享平台进行纠错和维护。

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