# 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:** Hubei Zhencheng Nonwoven Products Co., Ltd.
**Address:** Yanggang Industrial Park, Shazui Office, Xiantao, Hubei, China

## Conformity Assessment

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

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

## Product Information

**Name:** Shoe Cover
**Model:** Non woven shoe cover, PE/CPE shoe cover
**GMDN:** 15056
**Basic UDI-DI:** /
**Classification:** Class I
**Rule:** Rule 1, Annex VIII, Regulation (EU) 2017/745

## Declaration

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

**Remark**

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

Signature: Date: 2021年3月1日

Position: General Manager Place: Hubei / China

*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)*

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ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 14683:2019+AC:2019 Type IIR

## Product Information

**Name:** Disposable Medical Face Mask
**Model:** earloop type, ties type
**GMDN:** 35177
**Basic UDI-DI:** /
**Classification:** Class I
**Rule:** Rule 1, Annex VIII, Regulation (EU) 2017/745

## Declaration

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

**Remark**

*The declaration of conformity is valid in connection with the release technical document CE/MDR-HBZC-01.*

*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.*

Signature: 总经理 Date: 2021年3月1日

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

Position: General Manager Place: Hubei / China

Sungo global service

*Authorized Signature (S)*

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## 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: 2019
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-HBZC-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.*

*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:** Hubei Zhencheng Nonwoven Products Co., Ltd.
**Address:** Yanggang Industrial Park, Shazui Office, Xiantao, Hubei, China

## Product Information

**Name:** Non woven cap
**Model:** mob cap, bouffant cap, doctor cap, round cap
**GMDN:** 32297
**Basic UDI-DI:** /
**Classification:** Class I
**Rule:** Rule 1, Annex VIII, Regulation (EU) 2017/745

## 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: 湖北振成无纺布制品有限公司 Date: 2021年3月1日

Position: General Manager Place: Hubei / China