



## DECLARATION OF CONFORMITY

Regulation (EU) 2016/425 on Personal Protective Equipment (PPE)

**Manufacturer:** Unimax Medical Products Co., Ltd.  
**Address:** Special No.1 Liansai Road, Changshangkou Town,  
433024 Xiantao City, Hubei Province, P. R. China.  
**EU Representative:** SUNGO Europe B.V.  
**Address:** Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan  
den IJssel, The Netherlands.  
**Product Name** Disposable Clothing  
**Model:** Isolation Gown / Visitor Gown, Coverall, Lab Coat,  
Jacket, Kimono  
**Ref.** 400027,400071,400073,400026,400070,400072  
400015,400016,400017,400018,400019,400020,400021  
400022,400023,400024,400069,400025  
400031,400032,400033,400034  
**Category:** Category I  
**Conformity Assessment** Module A according to Annex IV of PPE Regulation  
**Procedure:** 2016/425  
**Applicable Regulation:** Regulation (EU) 2016/425 on Personal Protective  
Equipment (PPE)

We herewith declare that the above-mentioned products meet the requirements of Regulation (EU) 2016/425 on Personal Protective Equipment (PPE) and following harmonized standards.

ISO 10993-1: 2018

ISO 10993-5: 2009

ISO 10993-10: 2021

EN ISO 13688: 2013

Signature: For and on behalf of  
UNIMAX MEDICAL PRODUCTS CO., LTD.  
聯賽醫用產品(湖北)有限公司

Date: 2022-12-11

Position: GM

Place: Hubei/ China

.....  
Authorized Signature(s)

*The declaration of conformity is valid in connection with the release technical document*

*CE/PPE-UNIMAX-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.*



## DECLARATION OF CONFORMITY

### Regulation (EU) 2016/425 on Personal Protective Equipment (PPE)

**Manufacturer:** Unimax Medical Products Co., Ltd.  
**Address:** Special No.1 Liansai Road, Changshangkou Town,  
433024 Xiantao City, Hubei Province, P. R. China.  
**EU Representative:** SUNGO Europe B.V.  
**Address:** Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle  
aan den IJssel, The Netherlands.  
**Product Name** Gloves  
**Model:** Plastic gloves,veteran gloves  
**Ref.:** 100203  
**Category:** Category I  
**Conformity Assessment** Module A according to Annex IV of PPE Regulation  
**Procedure:** 2016/425  
**Applicable Regulation:** Regulation (EU) 2016/425 on Personal Protective  
Equipment (PPE)

We herewith declare that the above-mentioned products meet the requirements of Regulation (EU) 2016/425 on Personal Protective Equipment (PPE) and following harmonized standards.

ISO 10993-1: 2018

ISO 10993-5: 2009

ISO 10993-10: 2021

EN ISO 13688: 2013

For and on behalf of  
UNIMAX MEDICAL PRODUCTS CO., LTD.  
聯賽醫用產品(湖北)有限公司

Signature: \_\_\_\_\_

Date: 2022-12-11

Position: GM

Authorized Signature(s)

Place: Hubei/ China

*The declaration of conformity is valid in connection with the release technical document CE/PPE-UNIMAX-07.*

*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.*



## DECLARATION OF CONFORMITY

### Regulation (EU) 2016/425 on Personal Protective Equipment (PPE)

**Manufacturer:** Unimax Medical Products Co., Ltd.  
**Address:** Special No.1 Liansai Road, Changshangkou Town,  
433024 Xiantao City, Hubei Province, P. R. China.  
**EU Representative:** SUNGO Europe B.V.  
**Address:** Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle  
aan den IJssel, The Netherlands.  
**Product Name** Overshoes  
**Model:** Non-woven Overshoes, Plastic Overshoes, Boot  
Covers  
**Ref.** 400041,400043,400044  
**Category:** Category I  
**Conformity Assessment** Module A according to Annex IV of PPE Regulation  
**Procedure:** 2016/425  
**Applicable Regulation:** Regulation (EU) 2016/425 on Personal Protective  
Equipment (PPE)

We herewith declare that the above-mentioned products meet the requirements of Regulation (EU) 2016/425 on Personal Protective Equipment (PPE) and following harmonized standards.

ISO 10993-1: 2018

ISO 10993-5: 2009

ISO 10993-10: 2021

EN ISO 13688: 2013

Signature: *For and on behalf of*  
UNIMAX MEDICAL PRODUCTS CO., LTD.  
聯賽醫用產品(湖北)有限公司

Date: 2022-12-11

Position: GM

Place: Hubei/ China

.....  
*Authorized Signature(s)*

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



## DECLARATION OF CONFORMITY

### Regulation (EU) 2016/425 on Personal Protective Equipment (PPE)

**Manufacturer:** Unimax Medical Products Co., Ltd.  
**Address:** Special No.1 Liansai Road, Changshangkou Town, 433024  
Xiantao City, Hubei Province, P. R. China.  
**EU Representative:** SUNGO Europe B.V.  
**Address:** Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den  
IJssel, The Netherlands.  
**Product Name** Head Wear  
**Model:** Bouffant Cap, Clip Cap, Astronaut Cap, Hood, Beard Cover,  
Peaked Cap, Chef Cap, Forage Cap  
**Ref. :** 400000,400001,400002,400004,400005,400059,400060,40004  
5,400046,400047,400048,400049,400061,400062,400006,4000  
07,400063,400064,400012,400065,400057,400014  
**Category:** Category I  
**Conformity Assessment Procedure:** Module A according to Annex IV of PPE Regulation 2016/425  
**Applicable Regulation:** Regulation (EU) 2016/425 on Personal Protective Equipment  
(PPE)

We herewith declare that the above-mentioned products meet the requirements of Regulation (EU) 2016/425 on Personal Protective Equipment (PPE) and following harmonized standards.

ISO 10993-1: 2018

ISO 10993-5: 2009

ISO 10993-10: 2021

EN ISO 13688: 2013

For and on behalf of  
UNIMAX MEDICAL PRODUCTS CO., LTD.  
聯賽醫用產品(湖北)有限公司

Signature: \_\_\_\_\_

Date: 2022-12-11

Position: GM

Authorized Signature(s)

Place: Hubei/ China

*The declaration of conformity is valid in connection with the release technical document CE/PPE-UNIMAX-03A.*

*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.*



## DECLARATION OF CONFORMITY

### Regulation (EU) 2016/425 on Personal Protective Equipment (PPE)

**Manufacturer:** Unimax Medical Products Co., Ltd.  
**Address:** Special No.1 Liansai Road, Changshangkou Town,  
433024 Xiantao City, Hubei Province, P. R. China.  
**EU Representative:** SUNGO Europe B.V.  
**Address:** Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle  
aan den IJssel, The Netherlands.  
**Product Name** Oversleeves  
**Model:** Non-woven Oversleeves, Plastic Oversleeves  
**Ref.** 400039,400040  
**Category:** Category I  
**Conformity Assessment** Module A according to Annex IV of PPE Regulation  
**Procedure:** 2016/425  
**Applicable Regulation:** Regulation (EU) 2016/425 on Personal Protective  
Equipment (PPE)

We herewith declare that the above-mentioned products meet the requirements of Regulation (EU) 2016/425 on Personal Protective Equipment (PPE) and following harmonized standards.

ISO 10993-1: 2018

ISO 10993-5: 2009

ISO 10993-10: 2021

EN ISO 13688: 2013

For and on behalf of  
UNIMAX MEDICAL PRODUCTS CO., LTD.  
聯賽醫用產品(湖北)有限公司

Signature: \_\_\_\_\_

Date: 2022-12-11

Position: GM

Authorized Signature(s)

Place: Hubei/ China

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



## DECLARATION OF CONFORMITY

### Regulation (EU) 2016/425 on Personal Protective Equipment (PPE)

**Manufacturer:** Unimax Medical Products Co., Ltd.  
**Address:** Special No.1 Liansai Road, Changshangkou Town,  
433024 Xiantao City, Hubei Province, P. R. China.  
**EU Representative:** SUNGO Europe B.V.  
**Address:** Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle  
aan den IJssel, The Netherlands.  
**Product Name** Apron  
**Model:** Non-woven Apron, Plastic Apron  
**Ref.:** 400038,400037,400036,400035  
**Category:** Category I  
**Conformity Assessment** Module A according to Annex IV of PPE Regulation  
**Procedure:** 2016/425  
**Applicable Regulation:** Regulation (EU) 2016/425 on Personal Protective  
Equipment (PPE)

We herewith declare that the above-mentioned products meet the requirements of Regulation (EU) 2016/425 on Personal Protective Equipment (PPE) and following harmonized standards.

ISO 10993-1: 2018

ISO 10993-5: 2009

ISO 10993-10: 2021

EN ISO 13688: 2013

For and on behalf of  
UNIMAX MEDICAL PRODUCTS CO., LTD.  
聯賽醫用產品(湖北)有限公司

Signature: \_\_\_\_\_

Date: 2022-12-11

Position: GM

Authorized Signature(s)

Place: Hubei/ China

*The declaration of conformity is valid in connection with the release technical document CE/PPE-UNIMAX-07.*

*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.*