

Gants de toilette molletonnés à usage unique Méditec

Avantages :

Gant à texture molletonnée, absorbant, non pelucheux, sans parfum, confortable et économique.

Dispositif non stérile, à usage unique, indiqué pour l'hygiène corporelle des patients en hôpitaux, établissements médicalisés, crèches, maternités et pour les soins à domicile.

Pratique et hygiénique pour le personnel soignant, il permet d'éviter les risques de contaminations croisées entre les patients.

Caractéristiques :

Matière :	Fibres 100% polyester, matériau non-tissé Sans latex
Coloris :	Blanc
Taille :	Taille unique, longueur 23 cm, largeur 15 cm, tolérance +-1cm
Poids /grammage :	75gr./m2, tolérance +-3 gr.
Résistance :	Résistance au déchirement, à sec : $\geq 77N/5\text{ cm}$ Résistance au déchirement, en humidité : $\geq 65N/5\text{ cm}$ Résistance des bords soudés à l'ultrason, à sec : moyenne $\geq 35N$ Résistance des bords soudés à l'ultrason, en humidité : moyenne $\geq 35N$
Absorption :	Capacité d'absorption $\geq 700\%$
Indication :	Hygiène du patient en milieu médical et hospitalier.
Précaution :	Ne pas utiliser sur une peau lésée, lorsque le gant est souillé il doit être changé par un gant neuf.
Durée de vie :	Durée de vie du produit 5 ans
Stockage :	Conservation et stockage : Ne pas exposer à l'humidité, ni à une luminosité intense, ni au soleil, ni à l'ozone. Stockage sous une température comprise entre -5°C et 40°C
Emballage :	Sachet plastique, emballé sous-vide
Conformité :	Fabriqué sous un système qualité certifié ISO 9001 et ISO 13585 / CE

Référence : 115226 : conditionnement 50 unités / sachet
115227 : conditionnement 100 unités / sachet



FT 115226 / 115227 V01 01/2023

Nous nous réservons le droit de modifier les caractéristiques techniques de nos produits sans préavis. Documents et photos non contractuels



EC Declaration of Conformity



**Regarding Medical Device Directive(93/42/EEC)
including Directive 2007/47/EC**

Manufacturer

Manufacturer: Shanghai Chongjen Industry Co., Ltd

Address: Room 402, Building 37, No.258 Xinzhuan Road, CHJ Hi-Teck Park, Songjiang
District, Shanghai, 201612, China.

EU Rep

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam

Product

Name: Name: Disposable Nonwoven Products: Caps, Face Mask, Isolation Gown,
Coverall, Shoe Cover, Lab Coat, Nonwoven Glove, Beard Cover, Nonwoven Wipe;
Disposable PE Products: PE Glove, PE Apron, PE Shoe Cover, PE Sleeve, PE Gown

Type: See Annex of details

Classification: I
Rule: According to Rule 1

We confirm our product can meet the requirement of Medical Device Directive and the following harmonized standards.

EN ISO 14971:2012
EN ISO 15223-1:2012
EN 1041:2008
EN ISO 10993-1:2010
EN ISO 10993-5:2009
EN ISO 10993-10:2010

Signature:

Date:

2020.03.27

ANNEX

Disposable Nonwoven Products:

Product Name	Type
Face Mask	17.5*9.5cm, 14.5*9.5cm
Caps	18", 19", 21", 24", 28"
Isolation Gown	S:110*130cm, M:115*137cm, L:120*140cm, XL:125*145cm, XXL:130*150cm, XXXL:135*160cm
Coverall	S:161*65cm, M:164*67cm, L:167*67cm, XL:170*69cm, XXL:173*72cm, XXXL:176*74cm, XXXXL:178*76cm
Shoe Cover	Standard and nonskid 150*400mm, 180*420mm
Lab Coat	S:110*130cm, M:115*137cm, L:120*140cm, XL:125*145cm, XXL:130*150cm, XXXL:135*160cm
Non-woven Glove	Other sizes according to customer's requirement
Beard Cover	Other sizes according to customer's requirement
Non-woven Wipe	Other sizes according to customer's requirement

Disposable PE Products:

Product Name	Type
PE Glove	S/M/L/XL
PE Apron	80*140cm, Other sizes according to customer's requirement
PE Shoe Cover	15*36cm, 15*39cm
PE Sleeve	20cm*40cm / 20cm*46cm
PE Gown	80*140cm, Other sizes according to customer's requirement



Compliance Report

Applicant: Shanghai Chongjen Industry Co., Ltd.
Address: Room 402, Building 37, No.258 Xinzhuang Road, CHJ Hi-Tech Park, Songjiang District, Shanghai, 201612, China.

Product: Disposable Nonwoven Products: Caps, Face Mask, Isolation Gown, Coverall, Shoe Cover, Lab Coat, Nonwoven Glove, Beard Cover, Nonwoven Wipe;
Disposable PE Products: PE Glove, PE Apron, PE Shoe Cover, PE Sleeve, PE Gown.

Type: See annex for details

Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. 02586

Initial Issue Date: 10 Aug 2016

Tony Chen

General Manager (Signature)



Annex to Report (No. 02586)

Shanghai Chongjen Industry Co., Ltd.

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Disposable Nonwoven Products:	
Face Mask	17.5*9.5cm,14.5*9.5cm
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This annex is only valid if attached to the report mentioned above.