

Fornitura di Dispositivi di Protezione Individuale (DPI)

Stante la grave emergenza sanitaria in atto, come Macron abbiamo avviato il progetto “**Stop Covid-19/Macron #noicisiamo**” mettendo a disposizione la nostra filiera di produzione e distribuzione in Asia e Italia per realizzare **dispositivi di protezione individuali** quali ad esempio mascherine FFP2 e chirurgiche.

Tutti i prodotti sono rispondenti alle più stringenti normative e certificazioni, e tutto il processo di produzione è strettamente monitorato dagli ispettori dipendenti di Macron attivi sul territorio.

Ad oggi stiamo collaborando con varie Istituzioni Pubbliche, tra cui Protezione Civile-Sanità Emilia-Romagna e Campania oltre al Comando Generale dei Carabinieri.

E' tutto già pronto e in moto. Saremmo ovviamente felici di metterci anche a Vostra disposizione.

Premesso che stiamo cercando di negoziare le migliori tariffe aeree (che ad oggi sono 6 volte le normali quotazioni di mercato ca. 12,50 USD/kg), al momento i costi per i vari dispositivi sono i seguenti:

Tipologia	Prezzo senza IVA	N. pezzi in una confezione
Disposable protective face mask Type I	0,70 € *	50
Protective FFP2 mask	3,25 € *	20

*Prezzi riservati usufruendo del codice promozionale che vi è stato comunicato.

I prezzi sopra indicati sono senza iva e includono, oltre al costo del dispositivo, i dazi e tutte le attività di gestione logistica e distribuzione. Tali prezzi potrebbero variare in funzione del costo di trasporto aereo.

Potrete inserire il vostro ordine direttamente sul sito www.stop-covid.macron.com.

Tempi di consegna ca. 5 giorni lavorativi dall'accettazione dell'ordine.

Acquisto minimo 10 confezioni, acquisto massimo 500 confezioni.

Spese di trasporto 6,99 euro a spedizione.

Per ogni confezione acquistata, Macron donerà 1 € alla Protezione Civile.

Rimaniamo a disposizione per eventuali chiarimenti e in attesa di Vostro riscontro.

I nostri più cordiali saluti





macron

TECHNICALSPORTSWEAR



Certificate of Compliance



No. 0H200314.GMTUD18

Test Report no. XMT0202001059LY/PPE

Certificate's
Holder:



Certification ECM
Mark:



Product: Govek Disposable Protective Mask
Model(s): Flat Face & KN95

Verification to: Standard:
EN 149:2001+A1:2009

related to CE Directive(s):
R 2016/425 (Personal Protective Equipment)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process. 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

Issuance date: 14 March 2020

Expiry date: 13 March 2025

Reviewer
Technical expert
Amanda Payne



Approver
ECM Service Director
Luca Bedonni



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شهادة - 증명서 - Certificat - 證明書 - Сертификат - Certificate





EC Declaration of Conformity

Manufacturer:

[Redacted]

We, the manufacturer, herewith declare that the products

Disposable Face Masks

meet the provisions of Directive 93/42/EEC.

The medical device has been assigned to class I according to Annex IX (III. Classification Rule 1 All non-invasive device are in Class I, unless one of the rules set out hereinafter applies) of the Directive 93/42/EEC. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

BCC Inc

Room 1101, Floor 11, Building I, Guoyingyuan, Xicheng District, Beijing, P.R.C.

**(Accreditation by UKAS is granted to BCC
for providing audits and certifications of ISO13485)
Certificate No.UKZB18MD20065R0M**

following the procedure relating to the EC Declaration of Conformity set out in Annex II (or Annex V) of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above-mentioned declaration of conformity is exclusively under the sole responsibility of

[Redacted]

Place, Date

2020. Jan. 2020

EC Declaration of Conformity

Legally Binding Signature, Function



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Compliance Report

Applicant: [REDACTED]
Address: [REDACTED]

Product: Coverall, Isolation Gown, Cap, Shoe Cover, Sleeve, Face
Mask, Surgical 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. 02690
Initial Issue Date: 21 April 2017

Tony Chen

General Manager (Signature)



Annex to Report (No. 02690)

XXX

Product Name	Type
Coverall	UMDNS Code: 20-346
Isolation Gown	UMDNS Code: 15-037
Cap	UMDNS Code: 13-882
Shoe Cover	UMDNS Code: 13-574
Sleeve	UMDNS Code: 16-146
Face Mask	UMDNS Code: 12-458
Surgical Gown	UMDNS Code: 11-901

This annex is only valid if attached to the report mentioned above.

This report is the property of NQA and should be returned to NQA upon request.

