

3 Ply Face Mask

3 Ply Disposable Protective Mask (Pack of 50), code: C19005

Pack of 50 3 Ply disposable protective masks tested to EN14683. 95% BFE protection or filtration rate. FDA approved and CE marked. These masks are ideal for medical and general public use.

- Tested to EN14683
- >95% Particle Filtration
- CE marked
- Built in adjustable nose clip
- 3 layers of protection
- Pack of 50





Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

[Redacted]

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

[Redacted]

Device Listing#: See annex

[Redacted] will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. [Redacted] makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. [Redacted]

[Redacted] assumes no liability to any person or entity in connection with the foregoing. Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. [Redacted]

[Redacted] is not affiliated with the U.S. Food and Drug Administration.


Executive Director

Issued: Mar. 16, 2020

[Redacted]

Expiration Date: Dec.31, 2020





Fiscal Year 2020

CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator Number: [REDACTED]

Listing No.:	Premarket Submission Number/Type	Code	Device Name(s)	Activities
[REDACTED]	Exempt	LYU	ACCESSORY, SURGICAL APPAREL	Manufacturer Repackager/Relabeler Foreign Exporter
[REDACTED]	Exempt	MSH	Respirator, surgical	Manufacturer Repackager/Relabeler Foreign Exporter

Executive Director

Issued: Mar. 16, 2020

[REDACTED]

Expiration Date: Dec.31, 2020



END OF THE ANNEX

CE Documentation Review



No. [REDACTED]

Holder: [REDACTED]

Review goal: Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

Product: Absorbent Cotton Sliver, Absorbent Cotton Ball, Absorbent Cotton Roll, Cotton Swab, Gauze Bandage, Gauze Block, Double Head Cotton Swab, Disposable Mask

Model(s): (see the following annex I)

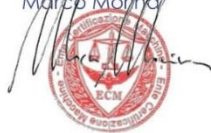
Classification: Class I
(accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. Test Report identified with the no. CE/MDD-KJ-2018. This document has been issued on voluntary basis and not as NB. Whereas the Manufacturer is responsible and not exempted to carry out all the necessary activities, as required by the Directive, before placing the CE Mark on the product.

Date of issue 14 September 2018

Expiry date 13 September 2023

Chief Manager
Marco Morini



Deputy Manager
Amanda Pavina



Ente Certificazione Macchine

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Annex I

No. [REDACTED]

Product Name	Type
Absorbent Cotton Sliver	1g/m, 1.5g/m, 2g/m, 3g/m, 4g/m, 5g/m, 6g/m, 7g/m, 8g/m, 9g/m, 10g/m, 12g/m, 15g/m, 20g/m.
Absorbent Cotton Ball	Large(0.8g~1.0g/grain), Medium(0.5g~0.7g/grain), Small(0.1g~0.4g/grain).
Absorbent Cotton Roll	1000g, 500g, 450g, 400g, 350g, 300g, 250g, 100g, 50g, 10g, 5g.
Cotton Swab	7cm, 8cm, 10cm, 12cm, 15cm, 20cm; 1 piece/bag, 2 pieces/bag, 4 pieces/bag, 5 pieces/bag, 6 pieces/bag, 8 pieces/bag, 10 pieces/bag, 15 pieces/bag, 20 pieces/bag, 25 pieces/bag, 30 pieces/bag, 40 pieces/bag, 45 pieces/bag, 50 pieces/bag, 70 pieces/bag, 80 pieces/bag, 90 pieces/bag, 100 pieces/bag.
Gauze Bandage	Classified by length: 200cm, 300cm, 350cm, 400cm, 450cm, 500cm, 600cm, 800cm, 1000cm, 1200cm according to the length. Classified by width: 4cm, 4.8cm, 6cm, 8cm, 10cm, 12cm, 15cm. Classified by the minimum number of packages: 1 piece, 2 pieces, 3 pieces, 4 pieces, 5 pieces, 8 pieces, 10 pieces.
Gauze Block	Length: 50mm, 60mm, 70mm, 80mm, 100mm, 120mm, 140mm, 150mm, 200mm; Width: 40mm, 50mm, 60mm, 70mm, 80mm, 100mm, 120mm, 140mm, 150mm. The number of folded layers is 8 layers.
Double Head Cotton Swab	7.5cm*100, 7.5cm*150, 7.5cm*200, 7.5cm*300, 7.5cm*350, 7.5cm*500.
Disposable Mask	17cm*8cm, 17cm*9cm, 17cm*9.5cm, 17cm*10cm, 17.5cm*8cm, 17.5cm*9cm, 17.5cm*9.5cm, 17.5cm*10cm, 18cm*8cm, 18cm*9cm, 18cm*9.5cm, 18cm*10cm, 19.5cm*8cm, 19.5cm*9cm, 19.5cm*9.5cm, 19.5cm*10cm.

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