

Workshop



Certificates



Certificate of Compliance



No. 00200330G.GBM0D15

Test Report no. EC-2020-0330-0415

Certificate's Holder: Guangzhou Boyan Medical Equipment Technology Co. , Ltd.
No. 30 North Jingu Road, Huadu District, Guangzhou City

Manufacturer: Guangzhou Boyan Medical Equipment Technology Co. , Ltd.
No. 30 North Jingu Road, Huadu District, Guangzhou City

Certification ECM Mark:



Product: KN 95 Mask
Model(s): 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, and if necessary, must refer to a Notified Body. 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: 30 March 2020

Expiry date: 29 March 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

Ente Certificazione Macchine Srl

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Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

GUANGZHOU BOYAN MEDICAL EQUIPMENT TECHNOLOGY CO., LTD.

No. 30 North Jingu Road, Huadu District, Guangzhou City

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

Owner/Operator Number: 10067319

Device Listing#: See annex

HRC 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. HRC 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.

HRC 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, HRC is not affiliated with the U.S. Food and Drug Administration.



Andy Sun

Chief engineer

Issued: April 6, 2020

Expiration Date: December 31, 2020

Display



Packing



Individually bagged
Weight:5.5g



40 bags/box
Size:220*124*130mm
Weight:282g

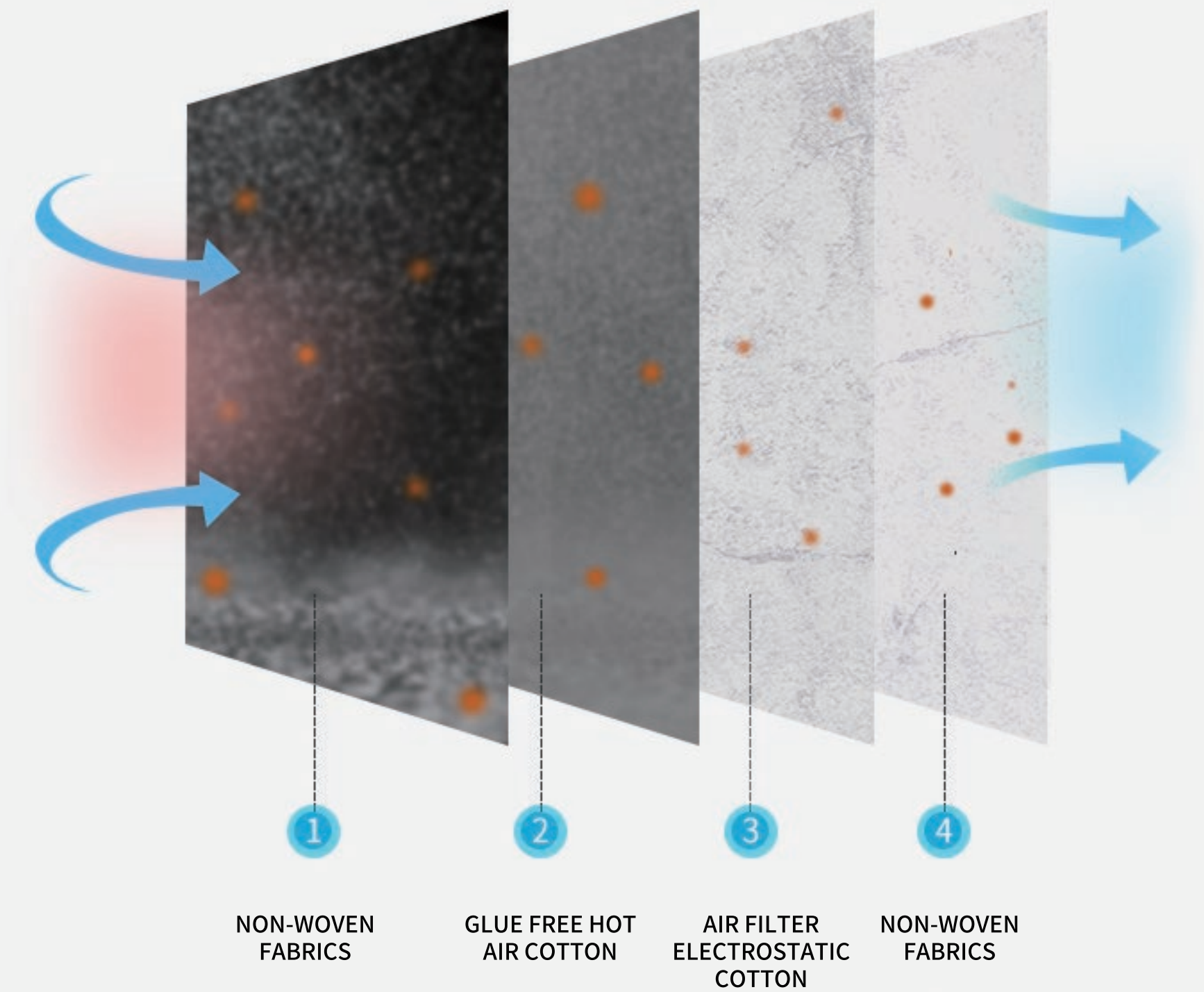


24boxes/carton
Size:520*460*415mm
Weight:8.22kg

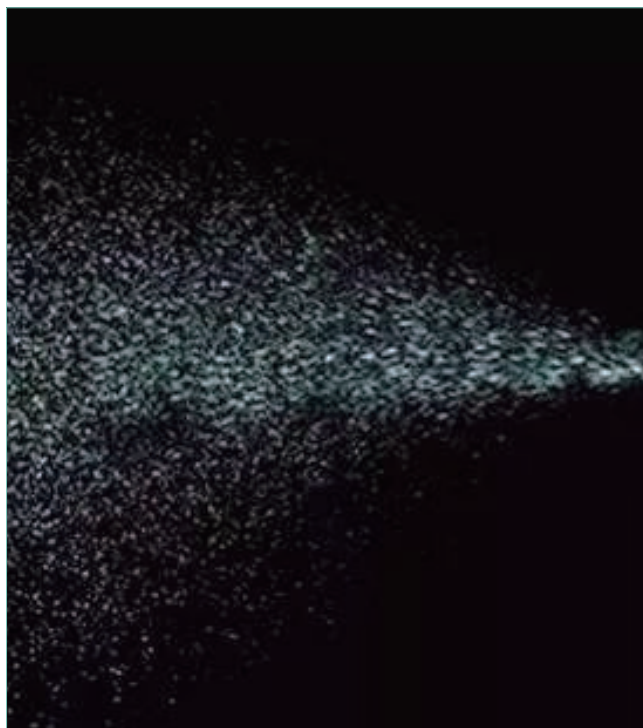


Each box contains 24 boxes of masks, totalling 960 masks and weighing 8.22kg.

APPLICATION



Resisting dust



Resisting droplet



Resisting pollen