CE DECLARATION OF CONFORMITY

Product Family Name: Surgical Face Masks

Device Name, Part Number: Single Use, Type I & II Surgical Face Mask REF FM3-1
Single Use, Type I, II, & IIR Surgical Face Mask, REF FM3-2

GMDN Code: 35177 Surgical Face Mask, Single-Use

UMDNS Code: 12458 Masks, Surgical

Applicable Council Directives: Medical Device Directive 93/42/EEC amended by 2007/47/EC

Risk Classification: Class I, Non-Sterile (Rule 1, MDD Annex IX)

Harmonized Standards to which conformity is declared:

Safety/Efficacy:	BS EN 14683:2019
Medical Device QMS:	EN ISO 13485:2016

OEM Manufacturer For: **Madison Medical Limited**
C/O Foshan Nanhai Plus Medical Co., Ltd
Shatou, Jiujiang Town, Nanhai District,
Foshan City, GUANGDONG, 528208
P.R. China

Authorized Representative in the European Community : For Madison Medical
Element Packaging LTD
Tallis House, 2 Tallis Street
London, EC4Y 0AB, United Kingdom

Notified Body: TUV Rheinland LGA Products GmbH
Tillystrabe 2, 90431 Nurnburg, Germany

This Device Family has been assessed with respect to the conformity assessment procedures described in Annex II excluding section 7 of Council Directive 93/42/EEC, as amended, and found to comply.

We declare, under our sole responsibility, that the above-mentioned products conform to the specified Directives and Standards and is eligible to carry the CE Mark. The Device History File is retained at the premises of the Manufacturer and its Authorized Representative.

Signature of Authorized Person:

吴晓东

Name Wu Xiao Dong
Head Quality & Regulatory Affairs/
Management Representative 吴晓东
Foshan Nanhai Plus Medical Co., Ltd

2020/04/14

Date Signed


3-PLY
50 PCS
DISPOSABLE SURGICAL
FACE MASK
AQUA CROSS
DISPOSABLE SURGICAL
FACE MASK
BFE≥99%
HIGH FILTRATION
CAPACITY
3 LAYERED
PROTECTION
FILTER POLLEN
DUST, BACTERIA
NO STIMULUS TO
HUMAN SKIN
SOFT, COMFORTABLE
ODOURLESS, BREATHABLE
3-PLY
50 PCS


AQUA CROSS
DISPOSABLE SURGICAL
FACE MASK


AQUA CROSS
DISPOSABLESURGICAL
FACE MASK
SOFT | BREATHABLE | SKIN FRIENDLY
Ideal for medical procedures and daily use.
Latex free. Low resistance to breathing.
BFE 99%, high filtration capacity.
3-PLY
50 PCS


Made in China

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Foshan Nanhai Plus Medical Co., Ltd
Shatou, Jiujiang Town,
Nanhai District, Foshan City
528208 Guangdong Province
China

has established and applies a quality management system for medical devices for the following scope:

(see attachment for scope)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-02-28
Certificate Registration No.:	SX 60132673 0001
An audit was performed. Report No.:	17024628 008
This Certificate is valid until:	2020-07-06

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date 2018-02-28

Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60132673 0001
Report No.: 17024628 008

Organization:
Foshan Nanhai Plus Medical Co., Ltd
Shatou, Jiujiang Town,
Nanhai District, Foshan City
528208 Guangdong Province
China

Scope:
Manufacture of Disposable Surgical Kits, Surgical Drapes, Surgical Gowns, Disposable Surgical Procedure Packs, Sterilization Wrap, Medical Face Masks;

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierung

Date: 2019-02-28

Dr. H. Lüdemann

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60132672 0001

Report No.: 17024628 008

Manufacturer:

Foshan Nanhai Plus Medical Co., Ltd
Shatou, Jiujiang Town,
Nanhai District, Foshan City
528208 Guangdong Province
China

Products:

Aspects of manufacture concerned with securing and maintaining sterile conditions of Sterile Surgical Drapes, Sterile Surgical Gowns, Sterile Disposable Surgical Procedure Packs, Medical Face Masks

Replaces Approval, Registration No.: DD 60120306 0001

Expiry Date: 2022-07-29

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-02-28

Date: 2019-02-28

Notified Body

Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Foshan Nanhai Plus Medical Co., Ltd.
Shatou Jiujiang Town, Nanhai District, Foshan City, Guangdong Province, China, 528208

Your notice of	Your reference	Date
18-03-2020		01-04-2020

Analysis Report 20.01616.05

Required tests :

EN 14683 (2019) + AC (2019)	**EN 14683 - annex B (2019) + AC (2019)**	**Bacterial filtration efficiency**
EN 14683 (2019) + AC (2019)	**EN 14683 - annex C (2019) + AC (2019)**	**Medical face masks - Breathability (differential pressure)**
EN 14683 (2019) + AC (2019)	**EN 14683 - §5.2.5 (2019) AC (2019)**	**Microbial cleanliness on masks**

Identification number	Information given by the client	Date of receipt
T2006094	SFMW01	18-03-2020

Sylvie Niessen
Order responsible

Reference: T2006094 - SFMW01

Bacterial filtration efficiency

Date of ending the test	27-03-2020
Standard used	EN 14683 - annex B (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Mask description	Nonwoven face mask, 3-ply: blue outside / white inside
Number of tested masks :	5
BFE Area tested :	± 49 cm²
Masks conditioning :	21 ± 5°C and 85 ± 5% RH
Side of the mask in contact with the bacterial challenge :	Inner side
Challenge bacterial strain used :	*Staphylococcus aureus* ATCC6538
Bacterial challenge per test :	1700 - 3000 CFU
Total test time :	1 min. delivering challenge + 1 min. without challenge (air flow continuing)
Flow rate :	28.3 l/min.
Positive control	Tests performed with no filter material in the air stream
Negative control	Test performed without challenge

Results

B = Bacterial filtration efficiency (%)

$$B = \frac{(C - T)}{C} \; X \; 100$$

With C = mean of the total plate counts for the positive control runs
T = total count for the tested mask

# Mask	B (%)
1	99.8
2	99.1
3	99.1
4	99.0
5	99.7

Mean particle size of the bacterial challenge aerosol : 2.8 µm

Controls

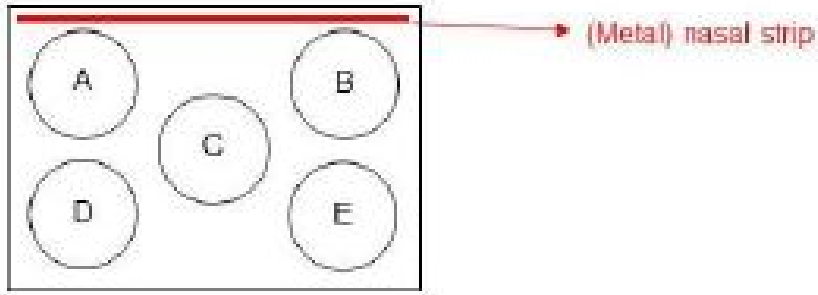
Mean positive controls 2307 CFU
Negative control < 1 CFU

Reference: **T2006094 - SFMW01**

Medical face masks - Breathability (differential pressure)

Date of ending the test	24-03-2020
Standard used	EN 14683 - annex C (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Mask description	Nonwoven face mask, 3-ply: blue outside / white inside
Number of tested masks :	5
Number of areas per mask	5 (see figure)
Dimension of the areas :	Disc whose diameter is 2.5 cm
Surface areas :	4.9 cm²
Flow rate :	8 l/min
Direction of the air flow :	From the inside of the mask to the outside
Masks conditioning :	21 ± 5°C and 85 ± 5% RH

Figure : Distribution of the areas in the mask



Results **Δ P**

	Mask 1	Mask 2	Mask 3	Mask 4	Mask 5
Area A	45.2	42.0	45.2	41.4	39.7
Area B	37.5	37.5	34.4	37.9	37.7
Area C	28.1	42.0	36.3	48.5	39.7
Area D	26.1	31.4	25.1	24.0	28.3
Area E	26.5	32.2	30.8	44.2	32.2
Average ΔP (Pa/cm²)	**32.7**	**37.0**	**34.4**	**39.2**	**35.5**

Reference: **T2006094 - SFMW01**

Microbial cleanliness on masks

Date of ending the test	30-03-2020
Standard used	EN 14683 - §5.2.5 (2019) AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Number of tested masks	5
Extraction liquid	Peptone 1g/l, NaCl 5g/l & Tween 20 2g/l
Extraction volume	300 ml
Extraction time	5 min.
Counting technique	Membrane filtration
Filtration volume	100 ml
Culture media	TSA (Tryptic Soy Agar) SDA (Sabouraud Dextrose Agar with chloramphenicol)
Incubation conditions	3 days at 30°C (TSA) 7 days at 20-25°C (SDA)

Results

# Mask	Mask weight (g)	CFU*/mask		Microbial cleanliness	
		Aerobic microbial count (bacteria)	*Fungi count (SDA)*	*Σ CFU/mask*	*Σ CFU/g*
1	3.26	30	<3	<33	<11
2	3.31	21	3	24	8
3	3.34	<3	<3	<6	<2
4	3.30	24	<3	<27	<9
5	3.31	<3	<3	<6	<2

Date: 01/03/2020

AUTHORISED DISTRIBUTOR LETTER

To whom it may concern:

This letter is to **CERTIFY**, the Following below mention is an **AUTHORISED DISTRIBUTOR** in the country of **The United Kingdom of Great Britain and Northern Ireland.**

For any assistance please contact:

Company Name:	**Element Packaging LTD**
Registered Address:	**Tallis House, 2 Tallis Street, London, EC4Y 0AB, United Kingdom**
Company Registration Number:	**09471486**
VAT Number:	**GB 223000973**
General Email Address:	**info@myelement.co.uk**
Telephone Number:	**+44 20 3633 0535**
Website:	**www.myelement.co.uk**

Element Packaging Limited has the responsibility to Promote, Distribute, Sale and Marketing and offer technical assistance for **Madison Medical Limited** .

This agreement is Effective: 01 March 2020 valid until 1st December 2022

If you have any questions please do not hesitate to contact me.

Best regards

Simon Tan
Business Development, VP
Madison Medical Limited

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