By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Wes Medical Care Manufacturing Pte Ltd
49 Joo Koon Circle, Level 2
Singapore 629068

Holds Certificate No: **MD 730501**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, storage and distribution of non-sterile surgical face mask

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-06-16
Latest Revision Date: 2020-06-16

Effective Date: 2020-06-16
Expiry Date: 2023-06-15

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2021

CERTIFICATE OF REGISTRATION

This certifies that:

WES MEDICAL CARE MANUFACTURING PTE. LTD.
49, Joo Koon Circle, Level-2
Singapore , SG 629068

is registered with the U.S. Food and Drug Administration for FY 2021 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number:	**10078084**
Device Classification Name:	**FACE MASK (EXCEPT N95 RESPIRATOR) FOR GENERAL PUBLIC/HEALTHCARE PERSONNEL PER IIE GUIDANCE**
Product Code:	**QKR**
Official Correspondent and U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp 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. Registrar Corp 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. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp

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info@registrarcorp.com • www.registrarcorp.com

David Lemarz
Executive Director
Registrar Corp
Dated: October 15, 2020

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00317706

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für Medizinprodukte, außer In-vitro-Diagnostika
Form for Medical Devices except In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority

Code
DE/CA22

Bezeichnung / Name
Bezirksregierung Münster, Dezernat 24

Staat / State **Deutschland**	Land / Federal state **Nordrhein-Westfalen**
Ort / City **Münster**	Postleitzahl / Postal code **48143**

Straße, Haus-Nr. / Street, house no.
Domplatz 36

Telefon / Phone **+49-251-4110**	Telefax / Fax **+49-251-4112525**

E-Mail / E-mail
mitteilungen-dimdi@brms.nrw.de

Anzeige / Notification

Registrierdatum bei der zuständigen Behörde Registration date at competent authority **14.10.2020**	Registriernummer / Registration number **DE/CA22/1311-520**

Typ der Anzeige / Notification type

☒ Erstanzeige / Initial notification

☐ Änderungsanzeige / Notification of change

☐ Widerrufsanzeige / Notification of withdrawal

Frühere Registriernummer bei Änderungs- und Widerrufsanzeige
Previous registration number if notification has been changed or withdrawn

Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG

☐ Hersteller / Manufacturer

☒ Bevollmächtigter / Authorised Representative

☐ Einführer / Importer

☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG

☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV
Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV

☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG
Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00317706

Anzeigender / Reporting organisation (person)			
	Code **DE/0000048589**		
	Bezeichnung / Name **MedNet EC-REP GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Münster**		Postleitzahl / Postal code **48163**
	Straße, Haus-Nr. / Street, house no. **Borkstrasse 10**		
	Telefon / Phone **025132266-61**		Telefax / Fax **025132266-22**
	E-Mail / E-mail **ear-admin@medneteurope.com**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Wes Medical Care Manufacturing Pte Ltd**		
	Staat / State **SG**		
	Ort / City **Singapore**		Postleitzahl / Postal code **629068**
	Straße, Haus-Nr. / Street, house no. **49, Joo Koon Circle, Level 2**		
	Telefon / Phone **+65 6565 5555**		Telefax / Fax
	E-Mail / E-mail		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **David Thaler**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Münster**		Postleitzahl / Postal code **48163**
	Straße, Haus-Nr. / Street, house no. **Borkstrasse 10**		
	Telefon / Phone **025132266-50**		Telefax / Fax
	E-Mail / E-mail **david.thaler@medneteurope.com**		

Vertreter / Deputy (optional)			
	Bezeichnung / Name **Ole Stein**		
	Telefon / Phone **025132266-16**		Telefax / Fax
	E-Mail / E-mail **ole.stein@medneteurope.com**		
	☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change		

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)

Klasse / Class

☒ I

☐ I - steril / sterile

☐ I - mit Messfunktion / with measuring function

☐ I - steril und mit Messfunktion / sterile and with measuring function

☐ IIa

☐ IIb

☐ III

☐ III - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012
manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012

☐ Aktives implantierbares Medizinprodukt / Active implantable medical device

☐ Aktives implantierbares Medizinprodukt - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012
Active implantable medical device - manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012

App (Software auf mobilen Endgeräten) ☐ ja / yes ☒ nein / no

Nummer(n) der Bescheinigung(en) / Certificate number(s)

Handelsname des Produktes / Trade name of the device
Premium Protective Face Masks, Premium Surgical Face Masks, Surgical Face Masks for Kids

Produktbezeichnung / Name of device
Face Mask 3-ply

Nomenklaturcode / Nomenclature code

Nomenklaturbezeichnung / Nomenclature term

Kategoriecode / Category code
10

Kategorie / Category
Produkte zum Einmalgebrauch

Kurzbeschreibung deutsch / German short description
3-Lagen-Gesichtsmasken sind für medizinische Zwecke bestimmt. Sie trägt zum Schutz von Patienten und medizinischem Personal bei, indem sie Mund, Nase und Kinn abdeckt und eine Barriere gewährleistet, die die Übertragung eines Infektionserregers wie Mikroorganismen, Körperflüssigkeiten und luftgetragenes Partikelmaterial begrenzt.
Die Gesichtsmasken sind Einwegprodukte zum einmaligen Gebrauch. Sie werden als Kontrollquelle für symptomatische Patienten verwendet, um die Ausbreitung von Atemtröpfchen, die durch Husten oder Niesen entstehen, zu verhindern.

Kurzbeschreibung englisch / English short description
3-Ply Face Mask are intended for medical purpose. It helps to protect patients and healthcare staff by covering the mouth, nose and chin, ensuring a barrier that limits the transmission of an infective agent such as microorganisms, body fluids, and airborne particulate material.
The Face masks are single use disposable device. Used as a source of control for patients who are symptomatic to prevent the spread of respiratory droplets produced by coughing or sneezing.

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)

☐ Semikritische Medizinprodukte / Semicritical medical devices
- ☐ Gruppe A / Group A
- ☐ Gruppe B / Group B

☐ Kritische Medizinprodukte / Critical medical devices
- ☐ Gruppe A / Group A
- ☐ Gruppe B / Group B
- ☐ Gruppe C / Group C

Nummer der Bescheinigung / Certificate number

Sterilisationsverfahren / Sterilisation procedures
- ☐ Dampfsterilisation / Steam sterilisation
- ☐ Gassterilisation / Gas sterilisation
- ☐ Strahlensterilisation / Radiation sterilisation
- ☐ andere / others

Angewandtes Verfahren / Applied procedure

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **Münster**

Datum
Date **2020-10-12**

Name **Maike Happe**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes
Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority

Bearbeiter / Person responsible	Telefon / Phone
Frau Silvia Wenge	**0251-4115936**

TEST REPORT: 7191237617-CHM20-01-RC

PSB Singapore

RESULTS

Sample description : Wes Care Premium Protective Face Masks

Test sample/ controls	Stage 1, CFU	Stage 2, CFU	Stage 3, CFU	Stage 4, CFU	Stage 5, CFU	Stage 6, CFU	Sum of Total plate count for the 6 sieves, CFU	Average Count for Controls, CFU	BFE (%)	Average BFE (%)
-ve Control	0	0	0	0	0	0	0			
+ve Control 1	160	461	756	636	367	169	2549	2603		
+ve Control 2	117	487	736	645	468	204	2657			
Sample 1	0	0	0	0	0	4	4		99.85	99.90
Sample 2	0	0	0	1	0	2	3		99.88	
Sample 3	0	0	0	0	0	3	3		99.88	
Sample 4	0	0	0	1	0	1	2		99.92	
Sample 5	0	0	0	0	0	1	1		99.96	

DESCRIPTION OF SAMPLE

One sample of mask labelled as "Wes Care Premium Protective Face Masks" was submitted by the above company.

METHOD OF TEST

BS EN 14683:2019 "Medical face masks – Requirement and test methods" Annex B – Method for *in vitro* determination of bacterial filtration efficiency (BFE)

Area contacting with the bacterial challenge: Inside of the mask
Flowrate: 28.3 ± 0.3 L/min
Mean particle size of the challenge aerosol: 3 µm ± 0.3 µm
Test area: Approximately 50 cm^2

TEST REPORT

(This Report is issued subject to the terms & conditions set out below)

Setsco Services Pte Ltd
18 Teban Gardens Crescent
Singapore 608925
Tel : (65) 6566 7777
Fax: (65) 6566 7718
www.setsco.com
Business Reg. No. 196900269D

Manufacturer: Wes Medical Care Manufacturing Pte Ltd

Brand/ Model: KF DESIGN FACE MASKS

Sample Description: Wes-Cares 3D Premium Face Masks

Results:

Test sample / Controls	Stage 1, CFU	Stage 2, CFU	Stage 3, CFU	Stage 4, CFU	Stage 5, CFU	Stage 6, CFU	Sum of plate count for each stage, CFU	Average plate count of the controls, CFU	Mean Particle Size[1] (µm)[1]	BFE (%)[2]
Negative Control (Before)	0	0	0	0	0	0	0	0		
Negative Control (After)	0	0	0	0	0	0	0			
Positive Control 1	150	331	354	535	423	129	1922	1887	2.83	
Positive Control 2	143	338	374	513	308	141	1817		2.93	
Positive Control 3	221	354	374	420	379	101	1849		3.14	
Positive Control 4	220	384	379	547	311	91	1932		3.18	
Positive Control 5	193	308	513	543	234	125	1916		3.12	
FB850016295901	0	0	0	0	0	0	0			100.0
FB850016295902	0	0	0	0	0	0	0			100.0
FB850016295903	0	0	0	0	0	0	0			100.0
FB850016295904	0	0	0	0	0	0	0			100.0
FB850016295905	0	0	0	0	0	0	0			100.0

Remarks:
The tested results apply only to the samples as received by the laboratory.
[1]Particle size to be in the range of 3.0 µm ± 0.3 µm.
[2]Based on the ASTM F2101– 19 Standard -- Level 1, percentage of Bacterial Filtration Efficiency (BFE) must be ≥ 95.

DR WU JIEN
HOD, MICRBIOLOGY

BIOLOGICAL & CHEMICAL TECHNOLOGY DIVISION