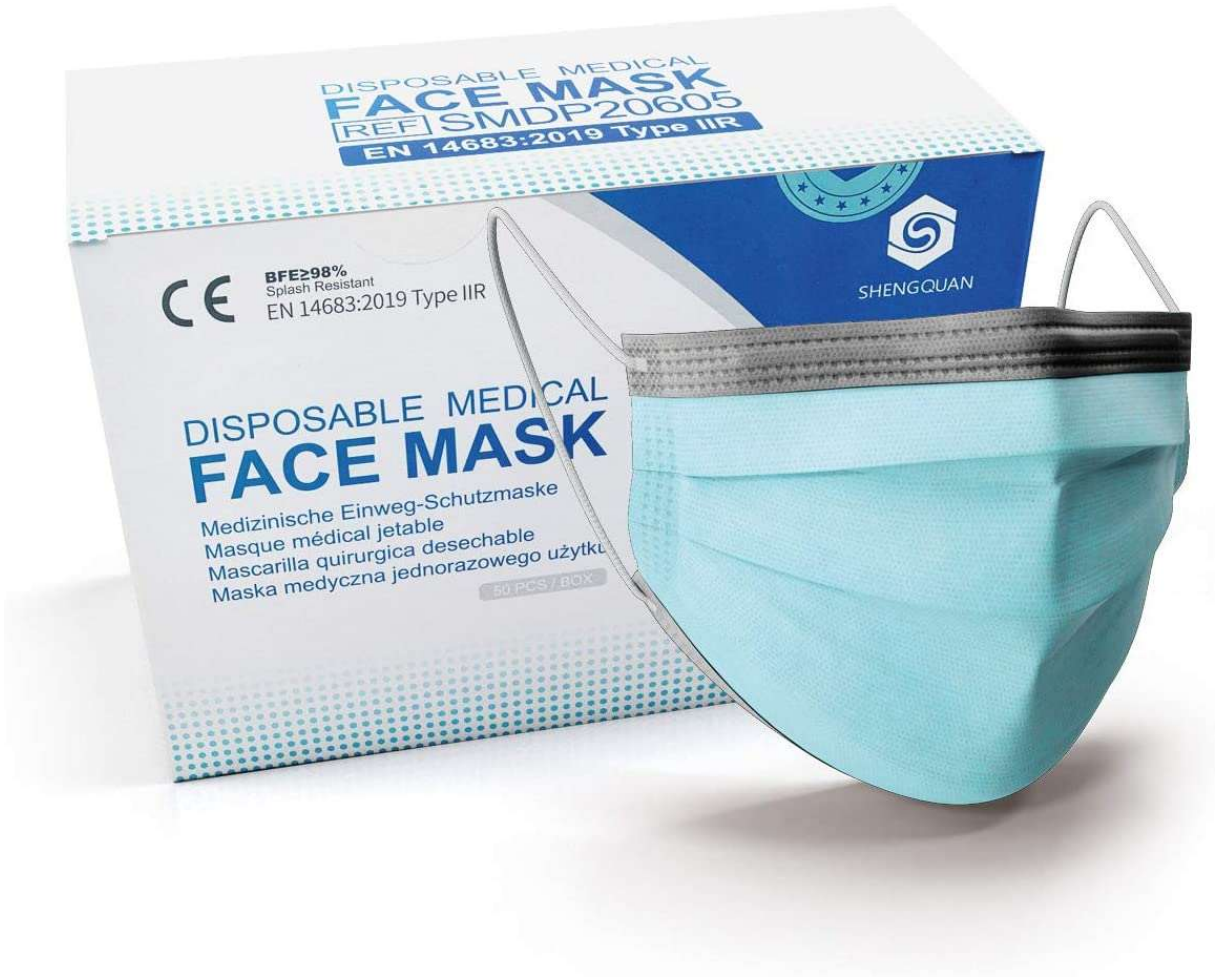
REF:SMDP20605



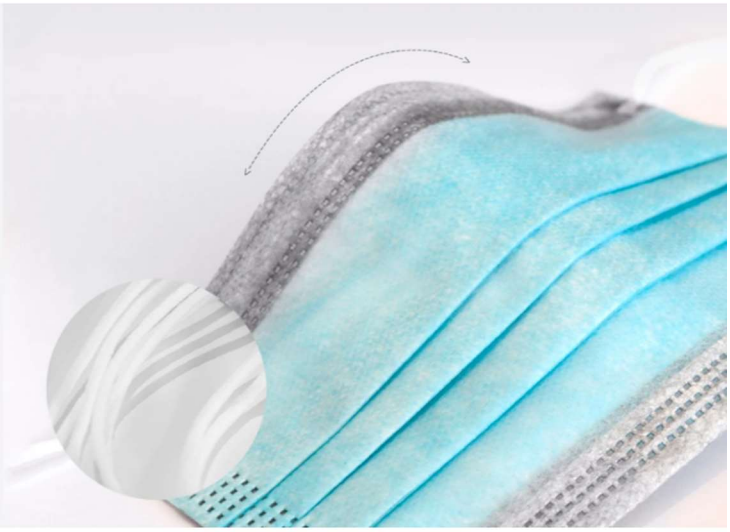
Medical Face Mask

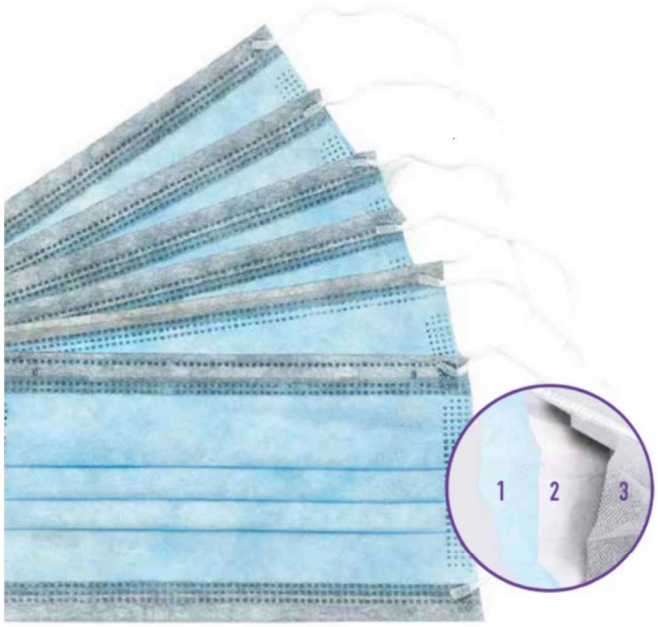
EN14683:2019 Type IIR

SQ Deutschland GmbH

KEY FEATURES

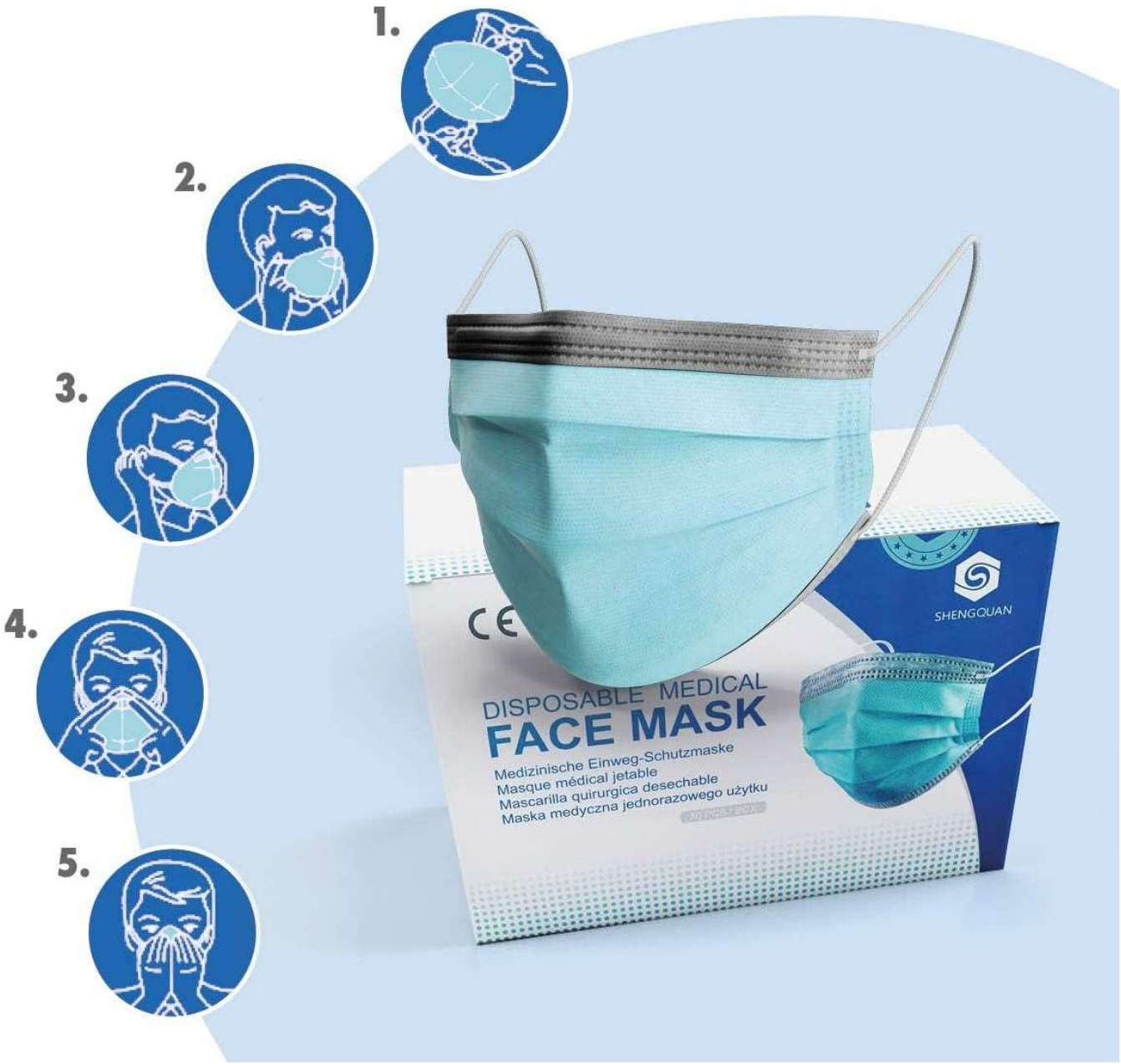
- ✓ ASTM Level 1 Surgical or Procedural Mask
- ✓ Meets FDA ASTM F2100-04 Standards
- ✓ Class 1 Flammability Rating
- ✓ ASTM Level 2 Synthetic Blood Resistance
- ✓ Not Made with Natural Rubber Latex



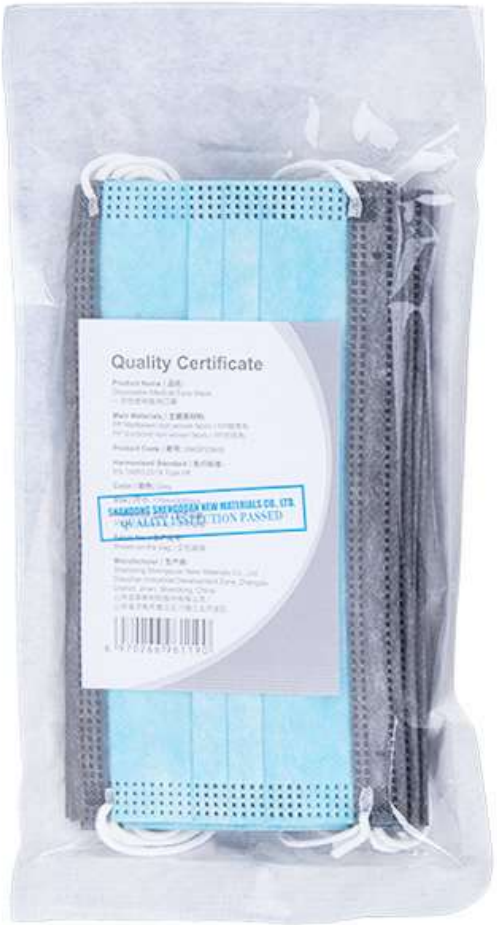


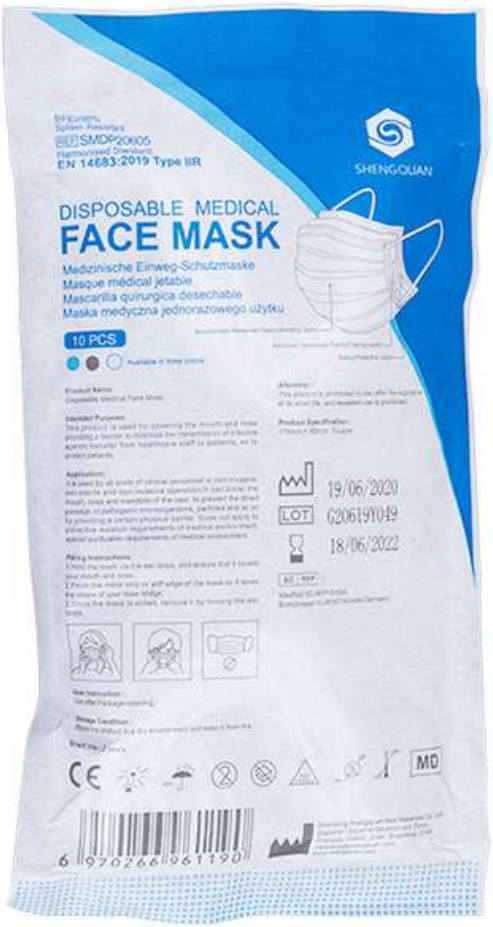
BIOMASS GRAPHENE DESIGN

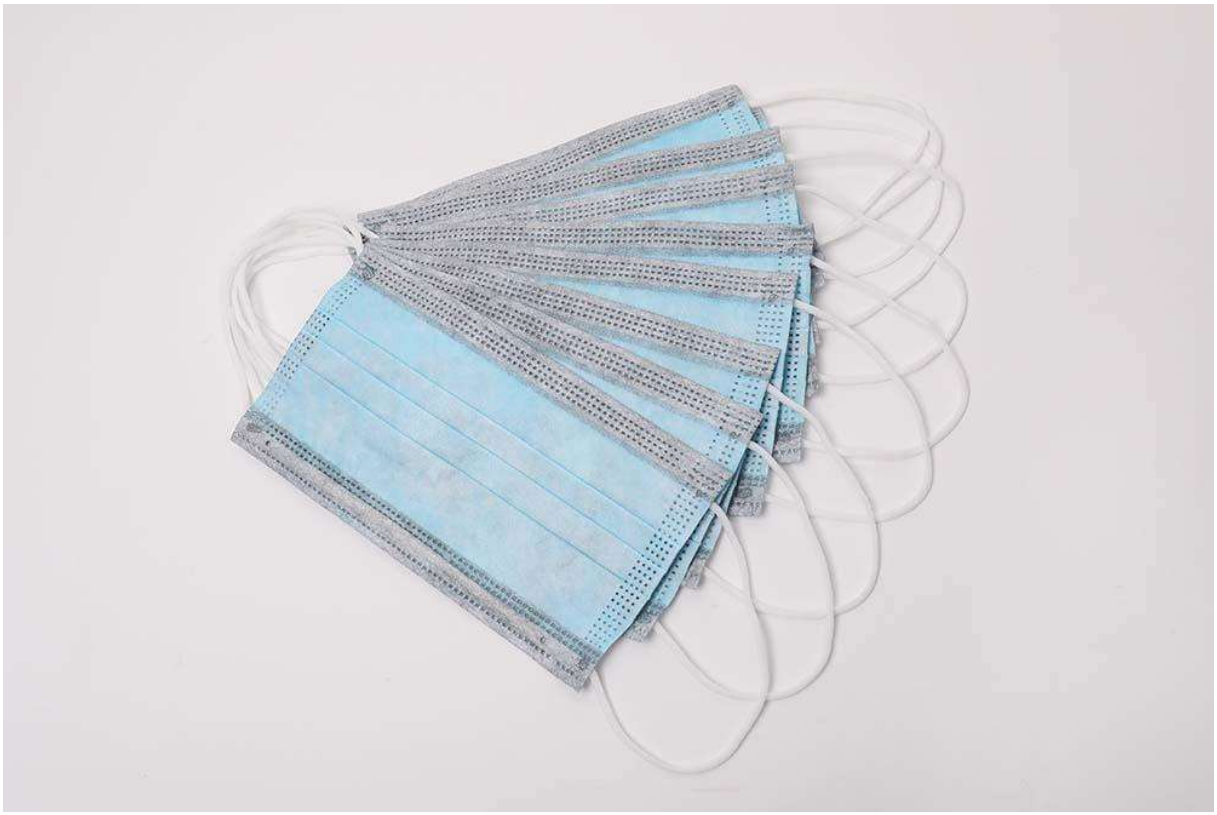
1. FIRST PLY
   Molding Layer
2. MIDDLE PLY
   Meltblown non-woven filtering layer
3. THIRD PLY
   Biomass graphene SS composite non-woven protective layer

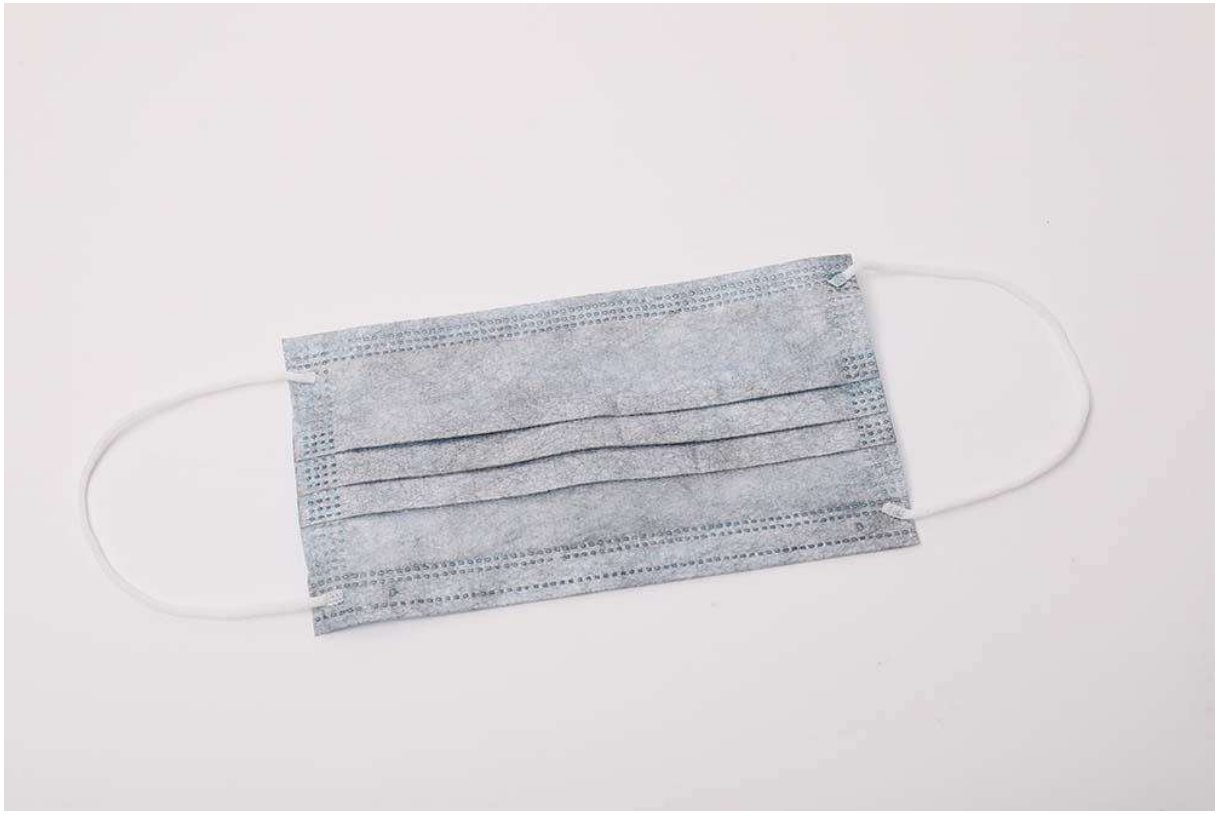


SQ Deutschland GmbH


Quality Certificate


SMDP20605
EN 14683:2019 Type IIR
SHENGQUAN
DISPOSABLE MEDICAL
FACE MASK
Medizinische Einweg-Schutzmaske
Masque médical jetable
Mascarilla quirúrgica desechable
Maska medyczna jednorazowego użytku
10 PCS
19/06/2020
LOT
C206191049
18/06/2022
MD
6 970266 961190





File No: SQ-MDD-13

CE

EC Declaration of Conformity
Regarding Medical Device Directive(93/42/EEC)

Manufacturer

Name: Shandong Shengquan New Materials Co., Ltd
Address: Diaozhen Industrial Development Zone, Zhangqiu, Jinan, Shandong, China

Authorized representative in the European Community

MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany

Product

Name: Disposable Medical Face Mask
Product Model: SMDP20605
Specification: 175mm × 95mm, 3-Layer
Classification: I
Rule: Annex IX rule 5 of the Directive 93/42/EEC
Conformity Assessment procedure: Annex Ⅶ of the Directive 93/42/EEC

We, the manufacturer declare on our sole responsibility that our product meets the requirements of Medical Device Directive and the following harmonized standards.

EN 14683:2019 Type IIR
EN ISO 14971:2012
EN ISO 15223-1:2016
ISO 10993-1:2018
EN ISO 10993-5:2009
EN ISO 10993-10:2010
EN 1041:2008
ISO 13485:2016

Place of issue: Jinan
Position: Management Representative
Signature:
Date: Xiumei Zhang Xiumei Zhang
2020.4.13

SQ Deutschland GmbH

SHANDONG SHENGQUAN NEW MATERIALS CO.,LTD
DIAOZHEN INDUSTRIAL DEVELOPMENT ZONE, ZHANGQIU, JINAN, CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)Face mask (Disposable Medical Face Mask)
Style No.	:	SMDP20605
Sample Color	:	(A) blue and grey
Lot No./Batch No.	:	Not provided
Proposed Care Instruction	:	-
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Apr 07, 2020
Testing Period	:	Apr 07, 2020 - Jul 14, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

3rd Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods

Clause 5.2 Performance Requirement

Clause 5.2.6 Biocompatibility
(ISO 10993-1)

Tests for in vitro cytotoxicity (test on extracts)*
(ISO 10993-5:2009)

Cell line
Mouse fibroblast cells L929 was purchased from cell bank of Chinese Academy of Sciences, Shanghai.

Cell culture medium
1640 medium, supplemented with L-glutamine and 10% FBS.

Sample preparation
The test article was sterilized at 121℃ for 30 min and was extracted with 1640 Mediun in ratio of 3 cm^2/mL in 37℃ for 24h. Positive control： Polyurethane film containing 0.1% zinc diethyl-dithiocarbamate (ZDEC).

Test procedures
L929 cells were cultured in RPMI 1640 medium with 10% FBS and Penicillin-Streptomycin, and placed in cells incubater of 37 ℃ and 5.0% CO_2 .
L929 cells were seeded in 96-well plates and each well was added 100 μl cell solution in a density of 1×10^5/ml. Cells were treated with the extract of the test sample and 6 replicate wells were used.
After 24h treatment, 50 μl MTT solution were add to each wells. After incubation, washing and Isopropanol extraction, the absorbance of each well was detected at 570 nm with a spectrophotometer and cell viability were calculated.

Test results
Cytoxicity tests results of face mask

Group	Cell viability
Solution control	100%
Test article	93.86%
Positive control	0.63%

Conclusions
Under the conditions of this study, the negative controls and the positive controls in the test performed as anticipated, the cytotoxicity of the sample was grade 0, which is non-cytotoxic

Remark:
* This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CNAS (China National Accreditation Service for Conformity Assessment) L1009.

Animal Skin Irritant Test*
(ISO 10993.10-2010)

Test animal
Four healthy conventional New Zealand White Rabbits, female, 2.0-3.0 kg each, supplied by Shanghai KeShuo Experiment Animal Co.，LTD, Certificate No. SCXK(Hu)2017-0013). The animal feed were supplied by Huzhou Eastern Hope Animal Nutrition Food Co., LTD, license No. Zhe Feed Approval(2019)05022.

Test environment
Rabbit room of conventional condition. Certificate No. SYXK(Hu)2019-0033, room temperature 18-23℃, relative humidity 45-65%

Test Results
Tab.1

Rabbit Number	response	Observation time					
		24 h		48 h		72 h	
		Sample S	Contrast C	Sample S	Contrast C	Sample S	Contrast C
5013#	Erythema	0	0	0	0	0	0
	Edema	0	0	0	0	0	0
5014#	Erythema	0	0	0	0	0	0
	Edema	0	0	0	0	0	0
5015#	Erythema	0	0	0	0	0	0
	Edema	0	0	0	0	0	0

The Primary Irritation Score of the sample was 0.

Tab.2 Primary irritation index categories in a rabbit

Mean score	Response category
0～0.4	Negligible
0.5～1.9	Slight
2～4.9	Moderate
5～8	Severe

Conclusions
According to Primary irritation index categories in a rabbit, the sample was found to be a negligible irritant to rabbits' skin

Remark:
* This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CNAS (China National Accreditation Service for Conformity Assessment) L1009.

Skin Sensitisation test*
(ISO 10993-10:2010)

Test environment
Animal room of conventional condition. Certificate No. SYXK(Hu) 2019-0033, room temperature 20-22℃, relative humidity 45-65%.

Experimental animals
Guinea pigs，female，300-500g,, supplied by Shanghai KeShuo Experiment Animal Co.，LTD, Certificate No. SCXK(Hu)2017-0013). The animal feed were supplied by Jiangsu Xietong Medical bio-engineering Co. LTD. License No: Su Feed Approval(2014) 01008

Test results
Delayed hypersensitivity tests results of face mask

Group	Time(h)	Skin response				Sensitization rate %
		0	1	2	3	
Normal saline	24	5	0	0	0	0
	48	5	0	0	0	0
The test article	24	10	0	0	0	0
	48	10	0	0	0	0

Magnusson and Kligman scale Patch test reaction Grading scale

Patch test reaction	Scoring
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

Conclusions
Under the conditions of the study, the test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig

Remark:
* This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CNAS (China National Accreditation Service for Conformity Assessment) L1009.

The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

3rd Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00304828

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 **19.05.2020**		Registriernummer / Registration number **DE/CA22/1311-76**
	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		

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 **ecrep@medneteurope.com**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Shandong Shengquan New Material Co., Ltd**		
	Staat / State **CN**		
	Ort / City **Zhangqiu, Jinan, Shandong**		Postleitzahl / Postal code **.**
	Straße, Haus-Nr. / Street, house no. **Diaozhen Industrial Development Zone**		
	Telefon / Phone **+86 531 83511609**		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
	Produktbezeichnung / Name of device **Disposable Medical Face Mask**
	Nomenklaturcode / Nomenclature code
	Nomenklaturbezeichnung / Nomenclature term
	Kategoriecode / Category code **10**
	Kategorie / Category **Produkte zum Einmalgebrauch**
	Kurzbeschreibung deutsch / German short description **Dieses Produkt wird zur Abdeckung von Mund und Nase verwendet und stellt eine Barriere dar, um die Übertragung von Infektionserregern vom medizinischen Personal auf die Patienten zu minimieren, um so die Patienten zu schützen.**
	Kurzbeschreibung englisch / English short description **This product is used for covering the mouth and nose providing a barrier to minimize the transmission of infective agents transfer from healthcare staff to patients, so to protect patients.**

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 **2020-05-11**

Name **Stephanie Vorwerk**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible **Frau Silvia Wenge**		Telefon / Phone **0251-4115936**