Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00300695

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/CA05**		
	Bezeichnung / Name **Behörde für Gesundheit und Verbraucherschutz, Referat V43**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20539**
	Straße, Haus-Nr. / Street, house no. **Billstraße 80**		
	Telefon / Phone **+49-40-428280**		Telefax / Fax **+49-40-427310017**
	E-Mail / E-mail **medizinprodukte@bgv.hamburg.de**		

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **09.04.2020**		Registriernummer / Registration number **DE/CA05/MP-238321-2557-00**
	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Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		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/0000040627**		
	Bezeichnung / Name **Shanghai International Holding Corporation GmbH (Europe)**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20537**
	Straße, Haus-Nr. / Street, house no. **Eiffestrasse 80**		
	Telefon / Phone **+49-40-2513175**		Telefax / Fax **+49-40-255726**
	E-Mail / E-mail **shholding@hotmail.com**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Hunan EEXI Technology&Service Co.,Ltd.**		
	Staat / State **CN**		
	Ort / City **Hunan**		Postleitzahl / Postal code **410323**
	Straße, Haus-Nr. / Street, house no. **No.6, North of Pingtou road, Liuyang Hi-tech Industrial Development Zone,**		
	Telefon / Phone **+86-731-83371666**		Telefax / Fax
	E-Mail / E-mail **overseas01@idore.com.cn**		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **Liang Jin**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20537**
	Straße, Haus-Nr. / Street, house no. **Eiffestr.80**		
	Telefon / Phone **+49-40-2513175**		Telefax / Fax **+49-40-255726**
	E-Mail / E-mail **shholding@hotmail.com**		

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	☐ 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 **EEXI**
	Produktbezeichnung / Name of device **Disposable surgical mask**
	Nomenklaturcode / Nomenclature code **12-458**
	Nomenklaturbezeichnung / Nomenclature term **Maske, Chirurgie**
	Kategoriecode / Category code **10**
	Kategorie / Category **Produkte zum Einmalgebrauch**
	Kurzbeschreibung deutsch / German short description
	Kurzbeschreibung englisch / English short description **Disposable surgical mask is intended to be used for clinical staff and operation room doctors**

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 **Hamburg**

Datum
Date **2020-03-29**

Name
Min Fang

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority	
Bearbeiter / Person responsible **Frau Sylvia Frenzel**	Telefon / Phone **040 42837-2120**

Declaration of Conformity

Manufacturer: Hunan EEXI Technology & Service co.,LTD..
Address: No. 6 North of Pingtou Road, Liuyang Hi-tech Industrial Development Zone, Hunan China.

EC Representative: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Device Name and Type:
Device name: Disposable surgical face mask
Type: Type IIR

Classification and Conformity Route:
According to 93/42/EEC Annex IX, Rules 1, all non-invasive devices are in Class I, unless one of the rules set out hereinafter applies. The Conformity Route is Annex VII EC declaration of conformity.

We, Hunan EEXI Technology & Service co.,LTD. herewith declare on our exclusive responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC and 2007/47/EC for medical devices as transposed into national law. All supporting documentation is retained under the premises of the manufacturer.

The validity period of this declaration of conformity is limited by the issuing of a revised declaration of conformity after change of the product .

Harmonized Standards:
All applicable harmonized Standards (published in the Official Journal of the European Communities)
Please see Annex List.

Name/Position: Liuxiangfu /General Manager

Signature: _____ **Date:** 2020. 4. 3

Annex:

Harmonized Standards List

Standards	Standard's title
ISO 13485:2016	Medical Devices - Quality management systems - Requirement for regulatory purposes
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 15223-1: 2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
EN 1041:2008	Information supplied by the manufacturer of medical devices
MEDDEV 2.7.1: REV4.	Evaluation Of Clinical Data : A Guide For Manufacturers and Notified Bodies
EN 14683:2019	Medical face masks – Requirements and test methods
EN ISO 10993-1: 2009	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5: 2009	Biological evaluation of medical devices-Part 5: Test for In Vitro Cytotoxicity.
EN ISO 10993-10: 2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

Test Report

(Electronic version)

Verification Website: www.gttc.net.cn

Verification Code: TLNK-6353-44

No:20R000012 Issue Date: 2020-04-11

Applicant: HUNAN EEXI TECHNOLOGY&SERVICE CO.,LTD.
Address: NO.6, NORTH OF PINGTOU ROAD, LIUYANG HI-TECH INDUSTRIAL DEVELOPMENT ZONE, HUNAN, CHINA

Sample information:

Disposable surgical mask(non-sterile)

Quantity: one hundred pieces

Model: YX011

Classification: Type Ⅱ R

Standard Adopted:

EN 14683:2019+AC:2019 <Medical face masks-Requirements and test methods>

Date Received/Date Test Started: 2020-03-30

Conclusion:

Bacterial filtration efficiency (BFE)	M
Microbial cleanliness	M
Differential pressure	M
Splash resistance pressure	M

Note: "M"-Meet the standard's requirement "F"-Fail to meet the standard's requirement "---"-No comment

Remark:
The authorization of bacterial filtration efficiency (BFE), differential pressure, splash resistance pressure is not received from CNAS.
All the tested items are tested under the standard condition (except for indication).
Copies of the report are valid only re-stamped.
The experiment was carried out at No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.

Approved By: Nan Ma

Nan Ma Engineer

Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
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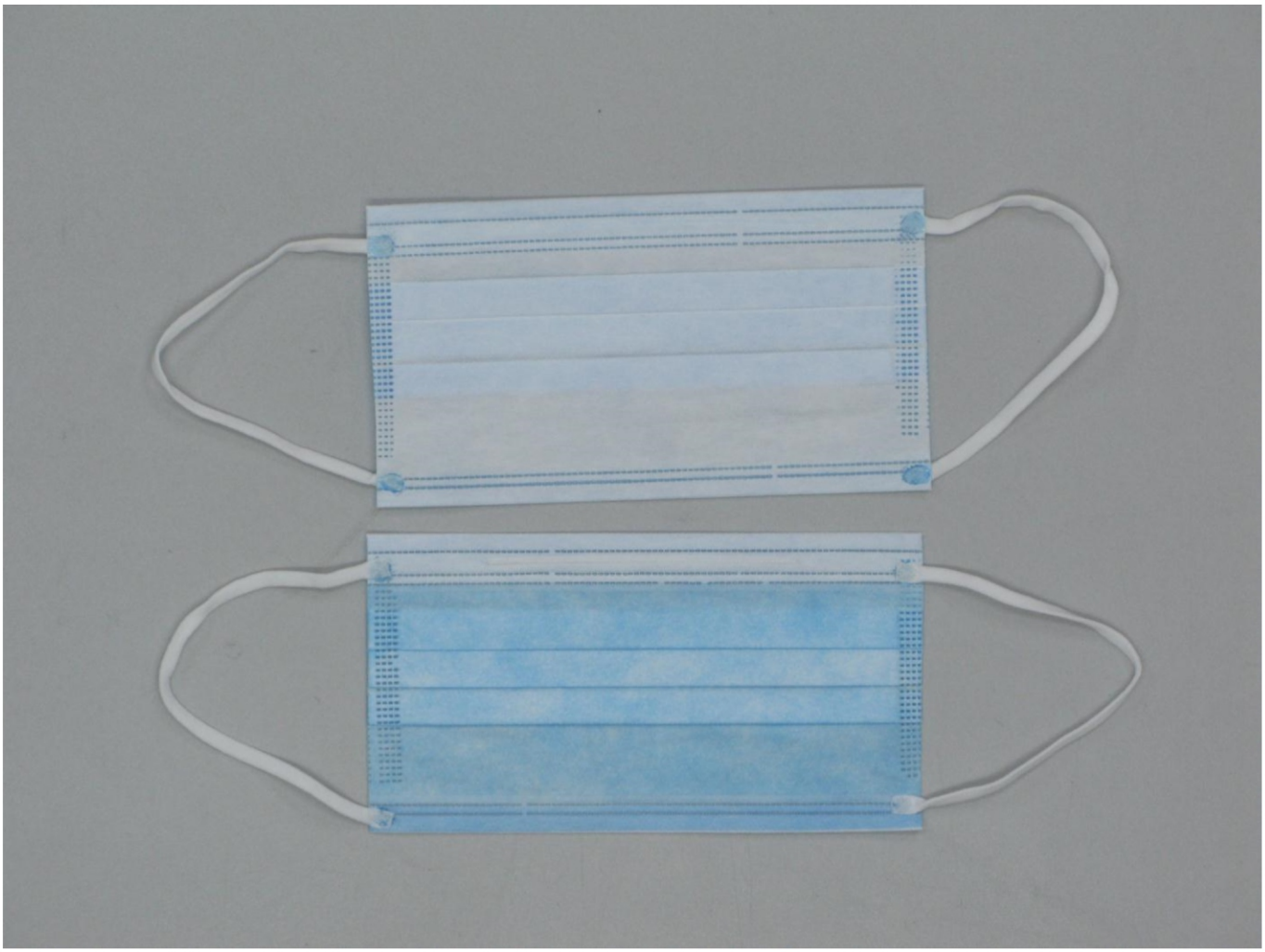
Test Report

(Electronic version)

No: 20R000012



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Test Report

(Electronic version)

No: 20R000012

Bacterial filtration efficiency (BFE)
Test method: EN 14683: 2019+AC: 2019 Annex B

Test principle:
A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency (BFE) of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Test equipment:
Incubator
Electronic balance
Autoclave
Experimental system for bacterial filtration efficiency (BFE) of mask

The environmental conditions of the laboratory and test condition:
Total bacteria: 0 CFU/plate
Total fungi: 0 CFU/plate
Blank experiment: Aseptic growth
Test environment temperature: 24.5℃, Relative humidity: 56.0%
Culture medium: TSA agar medium
Culture temperature: 37℃， Culture time: 48h
Test bacteria : staphylococcus aureus ATCC 6538
Concentration of bacterium: 5.0×10^5 CFU /ml
Positive control average (C): 1.9×10^3 CFU
Negative monitor count: ＜1 CFU
Test area: 40 cm^2
Flow rate: 28.3 l/min
Pretreatment: Condition each specimen for 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%
Mean particle size: 3.0 μm
The medical face mask in contact with the bacterial challenge: inside

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Test Report

(Electronic version)

No: 20R000012

Results:

Sample	T	BFE (%)	Requirement (%)	Classification	Conclusion
1	21	98.89	≥98 EN 14683:2019+AC:2019	Type ⅡR	Pass
2	25	98.68			
3	21	98.89			
4	21	98.89			
5	24	98.74			

Remarks:

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:

$B = (C - T) / C \times 100$

where

B is bacterial filtration efficiency (BFE), %;

C is positive control average;

T is the total plate count for the test specimen.

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Test Report

(Electronic version)

No: 20R000012

Microbial cleanliness
Test method: EN ISO 11737-1:2018, Membrane filtration

Test principle:
Take the required samples from the original packaging. Weigh a certain amount of sample and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl and 2 g/l Tween 20). The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0.45 µm filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) for fungi enumeration. The plates are incubated for 3 days at 30℃ and 7 days at (20 to 25)℃ for TSA and SDA plates respectively. The total bioburden is expressed by addition of the TSA and SDA counts.

Test equipment:
Constant temperature incubator
Electronic balance
Pressure steam sterilizer
Biosafety cabinet

The environmental conditions of the laboratory and test condition:
Test environment temperature: 24.5℃, Relative humidity: 56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth

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Test Report

(Electronic version)

No: 20R000012

Results:

Microbial	Measured value (CFU/g)	Microbial cleanliness (CFU/g)	Requirement (CFU/g)	Classification	Conclusion
Bacteria	3	3	≤30 EN 14683:2019+AC:2019	Type ⅡR	Pass
Fungi	0				

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Test Report

(Electronic version)

No: 20R000012

Differential pressure

Test method: EN 14683:2019+AC:2019 Annex C

Test principle:

This procedure was performed to evaluate the differential pressure of the medical face mask material by measuring the air exchange pressure through a measured surface area at a constant air flow rate.

Test equipment:

GTTC-YLC-1 Apparatus for measuring differential pressure

The environmental conditions of the laboratory and test condition:

Air flow: 8 l/min

Test area: 4.9cm^2

Pretreatment: Condition each specimen for a minimum of 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%

General location of the areas of the mask the differential measurements: specimen center

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Test Report

(Electronic version)

No: 20R000012

Results:

Sample	Measured value (Pa)	Differential pressure (Pa/cm^2)	Requirement (Pa/cm^2)	Classification	Conclusion
1	169	34.3	＜60 EN 14683:2019+AC:2019	Type ⅡR	Pass
2	163				
3	174				
4	170				
5	166				
Average	168				

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Test Report

(Electronic version)

No: 20R000012

Splash resistance pressure
Test method: ISO 22609:2004

Test principle:
A specimen medical face mask is supported on an apparatus. A volume of synthetic blood is sprayed horizontally at the specimen mask to simulate the scenario of a mask being splashed by a punctured blood vessel. The volume of fluid, distance to impact, orifice size and fluid velocity are defined in this method and intended to be consistent with this health care scenario. Any evidence of synthetic blood penetration on the side of the medical face mask contacting the wearer's face constitutes failure. Results are reported as "pass/fail". Specimen medical face masks are evaluated at a total of three different velocities corresponding to human blood pressures of 10.6 kPa, 16.0 kPa, and 21.3 kPa. Test results are reported at each velocity and the medical face mask is rated at the highest corresponding blood pressure for which medical face mask specimens demonstrate an acceptable quality limit of 4.0.

Test equipment:
Test apparatus for synthetic blood penetration LFY-227
Air compressor
Graduated cylinder
Electronic balance
Targeting plate

The environmental conditions of the laboratory and test condition:
Pretreatment: Condition each specimen for 24 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%
Surface tension of synthetic blood: 0.042 N/m
Pressure: 16.0 kPa
Velocity: 550 cm/s

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Test Report

(Electronic version)

No: 20R000012

Results:

Sample	Measured value	Requirement (kPa)	Classification	Conclusion
	Pressure			
	16.0 kPa			
1	pass	≥16.0 EN 14683:2019+AC:2019	Type Ⅱ R	Pass
2	pass			
3	pass			
4	pass			
5	pass			
6	pass			
7	pass			
8	pass			
9	pass			
10	pass			
11	pass			
12	pass			
13	pass			
14	pass			
15	pass			
16	pass			
17	pass			
18	pass			
19	pass			
20	pass			
21	pass			
22	pass			
23	pass			
24	pass			
25	pass			
26	pass			
27	pass			
28	pass			
29	pass			
30	pass			
31	pass			
32	pass			
Final result	pass			

Remarks:

An acceptable quality limit of 4.0 % is met for a single sampling plan when 29 or more of the 32 tested specimens show "pass" results.

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———End of Report———

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GTTC

检验检测报告 （电子版）

防伪查询网址：www.gttc.net.cn

防伪码：XPRL-7750-44

扫码下载报告

No:20R000525

委托单位	湖南一喜科技服务有限公司 地址：湖南浏阳高新技术产业开发区坪头北路6号3栋				
客户认定信息	医用外科口罩(非无菌型)　　100个 产品型号：YX011 等级：Tpye ⅡR ----------				
检验性质	委托检测	样品受理/测试开始日期	2020-04-15	报告签发日期	2020-04-16
判定依据	EN 14683:2019+AC:2019 《医用口罩 要求与测试方法》				
综合检验结论	---				

检验检测结果

检验检测项目	判定依据	判定
细菌过滤效率（BFE）	EN 14683:2019+AC:2019	符合
洁净度-微生物	EN 14683:2019+AC:2019	符合
压力差	EN 14683:2019+AC:2019	符合
抗合成血液穿透性	EN 14683:2019+AC:2019	符合

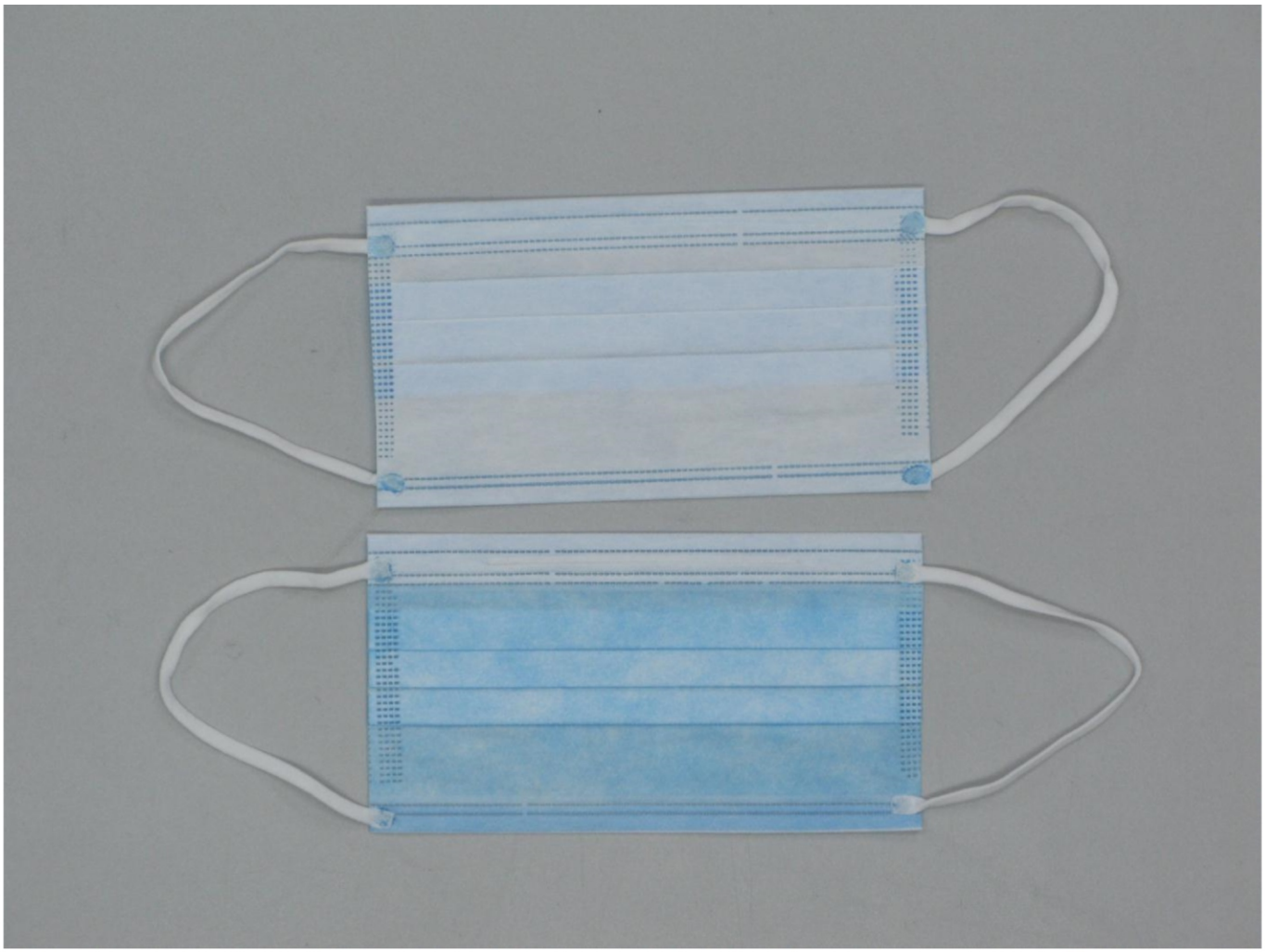
备注	注：细菌过滤效率（BFE）、压力差、抗合成血液穿透性项目暂未获得CNAS认可。 本报告为20R000012的中文版本。 本报告中检验检测项目均在相应标准规定的环境条件下进行（有注明的除外）。 复印件、副本未重新加盖报告书确认章无效。 本报告检验检测地址为广州市番禺区珠江路1号。

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

签发：马楠 工程师　　马楠

样品图片 （电子版）

No: 20R000525



广州检验检测认证集团有限公司 检验检测专用章 (GF2)

检验检测报告附页 （电子版）

No：20R000525

细菌过滤效率（BFE）

测试方法： EN 14683:2019+AC:2019 附录B

测试原理：

把口罩材料的试样夹在六联冲击采样器和气溶胶室之间。将金黄色葡萄球菌的气雾引入到气溶胶室，并在真空状态下通过口罩和采样器。口罩的细菌过滤效率（BFE）等于通过医用口罩材料的菌落形成单位数与气溶胶室中的菌落形成单位数的比值，用百分数表示。

测试设备：

恒温培养箱
电子天平
压力蒸汽灭菌锅
口罩细菌过滤效率（BFE）实验系统

实验室环境条件和测试条件：

细菌总数：0 CFU/皿
真菌总数：0 CFU /皿
空白实验：无菌生长
测试环境温度：24.5℃，相对湿度：56.0%
培养基名称：TSA琼脂培养基
样品培养温度：37℃，样品培养时间：48h
测试菌种：金黄色葡萄球菌ATCC 6538
菌液浓度：5.0×10^5 CFU /ml
阳性质控平均值（C）：1.9×10^3 CFU
阴性质控值：＜1 CFU
测试面积：40 cm^2
试样尺寸：15cm×15cm
气体流速：28.3 l/min
预处理方式：温度（21±5）℃、相对湿度（85±5）%环境中预处理24h
平均颗粒直径:：3.0 μm
口罩与细菌气溶胶接触面：里层

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

检验检测报告附页 （电子版）

No：20R000525

测试结果：

样品	T 计数之和	细菌过滤效率 (%)	技术要求 (%)	级别	单项结论
1	21	98.89	≥98 EN 14683:2019+AC:2019	Type ⅡR	符合
2	25	98.68			
3	21	98.89			
4	21	98.89			
5	24	98.74			

备注：

对于每个试样，按以下公式以百分比形式计算细菌过滤效率B：

$B = (C - T) / C \times 100$

式中

B---细菌过滤效率，%；

C---阳性质控平均值；

T---试验样品计数之和。

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

检验检测报告附页 （电子版）

No：20R000525

洁净度-微生物

测试方法： EN ISO 11737-1:2018 膜过滤法

测试原理：

从原始包装中取出所需样品，在无菌条件下称取一定量的样品装放到无菌瓶中，其中含有300ml的萃取液（1g/L的蛋白胨，5g/LNaCl和2g/L吐温20），在250rpm下振荡时间5min，量取100毫升萃取液，用0.45微米的薄膜过滤后，将滤膜放置到TSA平板上，用于测定细菌菌落总数，取100毫升萃取液，用0.45微米的薄膜过滤后，将滤膜放置到SDA平板上，用于测定真菌菌落总数。这些TSA和SDA平板分别在30℃下培养3天和20～25℃培养7天。总的微生物含量用TSA和SDA的计数和来表示。

测试设备：

恒温培养箱
电子天平
压力蒸汽灭菌锅
生物安全柜

实验室环境条件和测试条件：

测试环境温度：24.5℃相对湿度：56.0%
测试环境监控：细菌总数：0 CFU/皿，真菌总数：0 CFU/皿，空白实验：无菌生长

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

检验检测报告附页 （电子版）

No: 20R000525

测试结果:

微生物	实测值 (CFU/g)	洁净度-微生物 (CFU/g)	技术要求 (CFU/g)	级别	单项结论
细菌	3	3	≤30 EN 14683:2019+AC:2019	Type ⅡR	符合
真菌	0				

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

检验检测报告附页 （电子版）

No：20R000525

压力差

测试方法： EN 14683:2019+AC:2019 附录C

测试原理：

通过口罩压力差测试仪，抽取空气以恒定的流速通过已经测定表面积的医用口罩材料，从而测定空气交换的压力差。

测试设备：

GTTC-YLC-1口罩压力差测试仪

实验室环境条件和测试条件：

气体流量：8 l/min

试验面积：4.9cm^2

预处理方式：温度（21±5）℃、相对湿度（85±5）%环境中预处理大于4h

口罩压力差测试大概位置：试样中心

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

检验检测报告附页 （电子版）

No：20R000525

测试结果：

样品	实测值 (Pa)	压力差 (Pa/cm²)	技术要求 (Pa/cm²)	级别	单项结论
1	169	34.3	＜60 EN 14683:2019+AC:2019	**Type ⅡR**	符合
2	163				
3	174				
4	170				
5	166				
平均值	168				

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

检验检测报告附页 （电子版）

No：20R000525

抗合成血液穿透性

测试方法： ISO 22609:2004

测试原理：

医用面罩样品支撑在试验装置上。一定体积的合成血水平喷射到面罩样品上。模拟面罩被穿孔血管血液喷溅的场景。试验方法中确定了液体体积、喷射距离、喷口口径和喷射速度。使之与医学活动过程保持一致。在面罩与佩戴者脸部接触的一侧出现合成血的穿透，则面罩不合格。结果记录为“合格/不合格”。分别以血压10.6 kPa、16.0 kPa和21.3 kPa所对应的液体喷射速度对医用面罩样品进行试验。记录各喷射速度的试验结果。结合医用面罩可接受质量水平限为4.0对应的最高血压。

测试设备：

LFY-227合成血液穿透测试仪
空气压缩机
量筒
电子天平
定靶板

实验室环境条件和测试条件：

预处理条件：温度（21±5）℃、相对湿度（85±5）%环境中预处理24h
血液表面张力：0.042 N/m
压力：16.0 kPa
速度：550 cm/s

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

检验检测报告附页 （电子版）

No：20R000525

测试结果：

样品	实测值 压力 **16.0 kPa**	技术要求 (kPa)	级别	单项结论
1	符合	≥16.0 EN 14683:2019+AC:2019	Type ⅡR	符合
2	符合			
3	符合			
4	符合			
5	符合			
6	符合			
7	符合			
8	符合			
9	符合			
10	符合			
11	符合			
12	符合			
13	符合			
14	符合			
15	符合			
16	符合			
17	符合			
18	符合			
19	符合			
20	符合			
21	符合			
22	符合			
23	符合			
24	符合			
25	符合			
26	符合			
27	符合			
28	符合			
29	符合			
30	符合			
31	符合			
32	符合			
最终结果	符合			

备注：

单次取32个样品中有29或以上个样品为“合格”则符合4.0%可接受质量水平限。

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

———本报告结束———

医用外科非灭菌口罩属于CLASS 1的产品， 不需要也没有公告机构介入发证，没有公告机构的证书， 公告机构最多以他们的名义出测试报告和符合性声明。 效力和我们提供的测试报告和符合性声明是等同的。

国外客户进口清关时提供测试报告，符合性声明及注册表信息给进口国海关即可顺利清关

如有任何疑问，请参阅《欧盟主管当局通知》

Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context

Question 1: What is a medical device, active implantable medical device and an in vitro diagnostic medical device?

Medical devices are defined by Article 1 of the Medical devices directive (93/42/EEC),

Active implantable medical devices are defined by Article 1 of the Directive on active implantable medical devices (90/385/EEC),

In vitro diagnostic medical devices are defined by Article 1 of the Directive on *in vitro* diagnostic medical devices (98/79/EC),

Question 2: What are the legal requirements for placing such medical devices on the EU market and how should the compliance with them be verified and documented?

In order to place a medical device of any of the three types on the market, the manufacturer has to comply with the provisions of the applicable Directive mentioned under Q1.

Based on the level of potential hazard inherent in the type of device concerned the devices are classified in risk classes for which different types of conformity assessment procedures are applied.

For low risk devices, the manufacturer ensures and declares conformity with the applicable requirements. The Directives contain essential requirements that the device must satisfy and certain requirements on the technical documentation to be prepared by the manufacturer.

Medium and high risk devices (such as masks supplied in a sterile condition, ventilators, or diagnostic self-tests) require an intervention of a notified body which would in most cases need to assess both the manufacturer's quality management system and the specific device technical documentation prior to issuing a certification.

Notified bodies are listed in the NANDO (New Approach Notified and Designated Organisations) Information System,

Question 3: How can standards be used under the legislation?

The Directives lay down essential requirements on safety and performance of the devices they cover, but do not prescribe any specific mandatory technical solutions for the manufacturing and design of the devices. Therefore, the manufacturer can choose which technical solution to use to meet these essential requirements.

The Directives offer the possibility for manufacturers to rely on specific technical solutions, which are detailed in harmonised European standards or parts thereof. The references to these harmonised standards are published in the *Official Journal of the European Union*. Where a manufacturer chooses to follow a harmonised standard, the product is presumed to be in conformity with the applicable essential health, safety and performance requirements. The harmonised standards under the Medical devices directive most relevant for the public health crisis associated to the COVID-19 outbreak are listed in annex 1.

Most European standards for medical devices have their origin in international ISO or IEC standards. The annex 2 to this Q & A contains a table indicating the recognition of international standards under the legal systems of the member jurisdictions of the International Medical Device Regulators Forum (IMDRF).

Question 4: Where can standards be obtained?

Normally, manufacturers must purchase the standards they need from the national members of the European standardisation organisations in the field (CEN and CENELEC), i.e. the national standardisation bodies.

However, to ensure that European industry can quickly respond to the increased demand of medical devices generated by the public health crisis associated to the COVID-19 outbreak, the Commission has agreed with the European standardisation organisations that several standards are made freely and fully available by the national standardisation bodies.

Manufacturers can download these standards without cost from the online catalogues of the national standardisation bodies.

Question 5: Due to the urgency caused by the COVID-19 outbreak, is there a possibility to derogate from the normal conformity assessment procedures?

The directives prescribe that, on duly justified request, a Member State may, in the

interest of protection of health, authorize the placing on the market within the territory of the Member State concerned, of individual devices for which the conformity assessment procedures haven´t been carried out yet. The public health crisis associated to the COVID-19 outbreak is to be considered justified circumstance for that purpose.

In addition, the Commission Recommendation (EU) 2020/403 on conformity assessment and market surveillance of 13 March 2020 provides recommendations to Member States with regard to personal protective equipment and medical devices for protection (such as surgical masks, exploration gloves and some gowns). The recommendation is accompanied by a guidance document on conformity assessment procedures for protective equipment.

When assessing the need for a derogation, the national competent authority in a Member State may consider factors such as:

1. the degree of criticality of the use of the device for the protection of health;
2. availability of suitable substitutes;
3. documentation of compliance with a harmonised standard or other specific technical solutions ensuring fulfilment of the applicable essential requirements laid down in the relevant Directive;
4. review of reports of tests performed by competent bodies;
5. indications from vigilance and/or market surveillance.

The derogation should be temporary and the period of validity limited to what is strictly required for rendering the device compliant with the legislation or, if earlier, when suitable substitutes can be expected or the critical needs will no longer be present.

If Member States identify on the market devices for which the conformity assessment procedures have not been carried out and no valid derogation decision has been issued, they should take appropriate market surveillance measures in accordance with the relevant directive. Recent experience indicates that there is, in addition, a need to be attentive to falsified certificates and counterfeit devices.

Question 6: Is it necessary to register the devices?

In most cases there is an obligation for a manufacturer who makes devices available on the market to inform the competent authorities of the Member State in which he has his registered place of business, about the address of the registered place of business and the description of the devices concerned. Manufacturers outside the EU must have an authorised representative in the EU who then informs Member State competent authorities of the above.

Question 7: How can I get in touch with the national competent authorities?

The national competent authorities are listed here:

https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

Question 8: Off label use of a medical device

A medical device should be used as intended by the manufacturer and described in the instructions for use. If a device is used in any other way, this is considered 'off-label' use. Off-label use of a device could entail serious risks.

When it is deemed necessary to use an existing medical device for a purpose or in a way that is different from that intended by the manufacturer, risks and benefits to the patient must be carefully assessed. The assessment may typically include steps or factors such as:

- a documented risk assessment on the use of the device
- consideration of ethical and legal implications
- implementation of suitable precautions to minimise the risk
- reviewing the risk assessment at suitable periods
- obtaining approval from the national competent authorities when required.

Question 9: Will the new Regulations on medical devices and in vitro *diagnostic medical devices replace the three current Directives?*

The new Regulations (MDR[1] and IVDR[2]) will replace the current Directives 90/385/EEC and 93/42/EEC on 26 May 2020 and 98/79/EC on 26 May 2022.

In light of the public health crisis associated to the COVID-19 outbreak and with patient health and safety as a guiding principle, Commission adopted, on 3 April, a proposal to postpone the current application date of 26 May 2020 of the Medical

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

[2] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

Devices Regulation (MDR) for one year is ongoing. The Commission intends to submit the proposal to the co-legislators (the European Parliament and Council) in early April 2020 with the aim to have the proposal adopted before the end of May.

Information about the new Regulations is available at
https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en

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N.B. These Guidelines are intended solely for facilitating the application of Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC. However, the Commission accepts no responsibility or liability whatsoever with regard to the information in this document. This information provided in this document is:

- of a general nature only and is not intended to address the specific circumstances of any particular individual or entity;
- not necessarily comprehensive and complete;
- sometimes referring to actions of external actors over which the Commission services have no direct control and for which the Commission cannot assume responsibility;
- not of professional nature or should not be read as legal advice;
- to the extent that these Q&A:s may interpret legislation, the Commission's position is without prejudice to any interpretation of this legislation that may be issued by the Court of Justice of the European Union.

Annexes:

1. Harmonised standards under 93/42/EEC - Medical devices directive with relevance to COVID-19
2. Table indicating recognition of international standards under the legal systems of the member jurisdictions of the International Medical Device Regulators Forum (IMDRF) – based on information provided in 2019, updated with regard to EU Harmonised standards April 2020:
   https://ec.europa.eu/docsroom/documents/40606

Annex 1

Harmonised standards under 93/42/EEC – Medical Devices Directive with relevance to COVID-19

Name of harmonised standard according to 93/42/EEC - Medical Devices Directive	English title of harmonised standard according to 93/42/EEC - Medical Devices Directive
EN 14683: 2019+AC:2019	Medical face masks - Requirements and test methods
EN 455-1:2000	Medical gloves for single use - Part 1: Requirements and testing for freedom from holes
EN 455-2:2009+A2:2013	Medical gloves for single use - Part 2: Requirements and testing for physical properties
EN 455-3:2006	Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
EN 455-4:2009	Medical gloves for single use - Part 4: Requirements and testing for shelf life determination
EN 794-3:1998+A2:2009	Lung ventilators - Part 3: Particular requirements for emergency and transport ventilators
EN 1282-2:2005+A1:2009	Tracheostomy tubes - Part 2: Paediatric tubes (ISO 5366-3:2001, modified)
EN 1782:1998+A1:2009	Tracheal tubes and connectors
EN 12342:1998+A1:2009	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 13544-1:2007+A1:2009	Respiratory therapy equipment - Part 1: Nebulizing systems and their component
EN 13544-2:2002+A1:2009	Respiratory therapy equipment - Part 2: Tubing and connectors
EN 13544-3:2001+A1:2009	Respiratory therapy equipment - Part 3: Air entrainment devices
EN ISO 5359:2008	Low-pressure hose assemblies for use with medical gases (ISO 5359:2008) EN ISO 5359:2008/A1:2011

EN ISO 5366-1:2009	Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 1: Tubes and connectors for use in adults (ISO 5366-1:2000)
EN ISO 7376:2009	Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation (ISO 7376:2009)
EN ISO 7396-2:2007	Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems (ISO 7396-2:2007)
EN ISO 8185:2009	Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems (ISO 8185:2007)
EN ISO 9170-2:2008	Terminal units for medical gas pipeline systems - Part 2: Terminal units for anaesthetic gas scavenging systems (ISO 9170-2:2008)
EN ISO 9360-1:2009	Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 1: HMEs for use with minimum tidal volumes of 250 ml (ISO 9360-1:2000)
EN ISO 9360-2:2009	Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml (ISO 9360-2:2001)
EN ISO 10079-1:2009	Medical suction equipment - Part 1: Electrically powered suction equipment - Safety requirements (ISO 10079-1:1999)
EN ISO 10079-2:2009	Medical suction equipment - Part 2: Manually powered suction equipment (ISO 10079-2:1999)
EN ISO 10524-1:2006	Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO 10524- 1:2006)
EN ISO 10524-2:2006	Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators (ISO 10524-2:2005)
EN ISO 10524-3:2006	Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves (ISO 10524-3:2005)
EN ISO 10524-4:2008	Pressure regulators for use with medical gases - Part 4: Low-pressure regulators (ISO 10524- 4:2008)
EN ISO 10651-2:2009	Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 2: Home care ventilators for ventilator-dependent patients (ISO 10651- 2:2004)
EN ISO 10651-4:2009	Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators (ISO 10651-4:2002)

EN ISO 10651-6:2009	Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 6: Home-care ventilatory support devices (ISO 10651-6:2004)
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
EN ISO 10993-17:2009	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)
EN ISO 13408-1:2015	Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2008, including Amd 1:2013)
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018
EN 13795-1: 2019	Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns
EN 13795-2:2019	Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 15001:2011	Anaesthetic and respiratory equipment - Compatibility with oxygen (ISO 15001:2010)
EN ISO 15002:2008	Flow-metering devices for connection to terminal units of medical gas pipeline systems (ISO 15002:2008)
EN ISO 17510-1:2009	Sleep apnoea breathing therapy - Part 1: Sleep apnoea breathing therapy equipment (ISO 17510-1:2007)
EN ISO 17510-2: 2009	Sleep apnoea breathing therapy – Part 2 - Masks and application accessories
EN ISO 18777:2009	Transportable liquid oxygen systems for medical use - Particular requirements (ISO 18777:2005)
EN ISO 18779:2005	Medical devices for conserving oxygen and oxygen mixtures - Particular requirements (ISO 18779:2005)
EN ISO 21969:2009	High-pressure flexible connections for use with medical gas systems (ISO 21969:2009)
EN ISO 23328-1:2008	Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance (ISO 23328- 1:2003)
EN ISO 23328-2:2009	Breathing system filters for anaesthetic and respiratory

	use - Part 2: Non-filtration aspects (ISO 23328-2:2002)
EN ISO 23747: 2009	Anaesthetic and respiratory equipment -- Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans
EN ISO 26782: 2009	Anaesthetic and respiratory equipment -- Spirometers intended for the measurement of time forced expired volumes in humans
EN 60601-1: 2006	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005) EN 60601-1:2006/AC:2010 EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012)
EN 60601-1-1:2001	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems (IEC 60601-1-1:2000)
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014)
EN 60601-1-4:1996	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems (IEC 60601-1-4:1996) EN 60601-1-4:1996/A1:1999 (IEC 60601-1-4:1996/A1:1999)
EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)
EN 60601-1-8:2007	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006) EN 60601-1-8:2007/AC:2010 EN 60601-1-8:2007/A11:2017
EN 60601-1-11:2010	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard:

	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2010)
EN 60601-2-4:2003	Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators (IEC 60601- 2-4:2002)
EN 60601-2-12:2006	Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators (IEC 60601-2-12:2001)
EN 60601-2-17:2004	Medical electrical equipment - Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment (IEC 60601-2-17:2004)
EN 60601-2-24:1998	Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers (IEC 60601-2-24:1998)
EN 60601-2-52:2010	Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds (IEC 60601-2-52:2009) EN 60601-2-52:2010/AC:2011
EN 62304:2006	Medical device software - Software life-cycle processes (IEC 62304:2006) EN 62304:2006/AC:2008
EN 62366:2008	Application of usability engineering to medical devices
EN ISO 81060-1:2012	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007)