Technical Construction File
EN 14683:2019
Medical face masks - Requirements and test methods

Report reference No.	TMSH20031922943
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Date of issue	March 27,2020
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Manufacturer	Suzhou Keteng Medical Technology Co., Ltd.
Address	No.555 Beiling Road, Beiqiao Street, Xiangcheng District, Suzhou
Factory	The same as Manufacturer
Address	The same as Manufacturer
Standard	☒ EN 14683:2019
Review Report Form No.	14683
TRF originator	GTS
Master TRF	Reference No. EN 14683
Review procedure	GTS
Type of Review object	Disposable medical mask
Trademark	
Model/type reference	L, M, S
Rating	/

Possible review case verdicts: - review case does not apply to the test object.....: N(.A.) - review object does meet the requirement.....: P(ass) - review object does not meet the requirement.....: F(ail)
General remarks:
"(see remark #)" refers to a remark appended to the report. "(see appended table)" refers to a table appended to the report. Throughout this report a comma is used as the decimal separator. The review results presented in this report relate only to the object reviewed. This report shall not be reproduced except in full without the written approval of the third party.

Testing:	
Date of receipt of review item:	March 19,2020
Date(s) of performance of review:	March 19,2020 to March 27,2020

General product information:
Disposable medical mask

Summary of reviewing:

This review report includes:

Annex I: 1 page(s) of photo documentation.

Artwork of Marking Label

Disposable medical mask
Model No.: L, M, S
Standard: EN 14683:2019

CE

Suzhou Keteng Medical Technology Co., Ltd.
No.555 Beiling Road, Beiqiao Street, Xiangcheng District, Suzhou

4	Classification		--
	Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance.	Type I	P
5	Requirements		--
5.1	General		--
5.1.1	Materials and construction		--
	The medical Disposable medical maskis a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. The medical Disposable medical maskshall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness.	Not disintegrate, split or tear during intended use	P
5.1.2	Design		--
	The medical Disposable medical maskshall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides. Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).		P
5.2	Performance requirements		--
5.2.1	General		--
	All tests shall be carried out on finished products or samples cut from finished products.		P
5.2.2	Bacterial filtration efficiency (BFE)		--
	When tested in accordance with Annex B, the BFE of the medical Disposable medical maskshall conform to the minimum value given for the relevant type in Table 1.		P
5.2.3	Breathability		--
	When tested in accordance with Annex C, the differential pressure of the medical Disposable medical maskshall conform to the value given for the relevant type in Table 1.		P
5.2.4	Splash resistance		--
	When tested in accordance with ISO 22609:2004 the resistance of the medical Disposable medical maskto penetration of splashes of liquid shall	Not required	N/A

	conform to the minimum value given for Type IIR in Table 1.		
5.2.5	Microbial cleanliness (Bioburden)		--
	When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ⩽ 30 CFU/g tested (see Table 1).	⩽ 30 CFU/g	P
5.2.6	Biocompatibility		--
	According to the definition and classification in EN ISO 10993-1:2009, a medical Disposable medical maskis a surface device with limited contact. The manufacturer shall complete the evaluation of the medical Disposable medical maskaccording to EN ISO 10993-1:2009 and determine the applicable toxicology testing regime. The results of testing should be documented according to the applicable parts of the EN ISO 10993 series. The test results shall be available upon request.		P
6	Marking, labelling and packaging		--
	Annex I, § 13, of the Medical Devices Directive (93/42/EEC) or Annex I, § 23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical Disposable medical maskis supplied. The following information shall be supplied: a) number of this European Standard; b) type of mask (as indicated in Table 1). c) EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.	See packaging	--

- End of Review Report -

Type of equipment, model: Disposable medical mask
L, M, S

Details of:

View:

[X] general

[ ] front

[ ] rear

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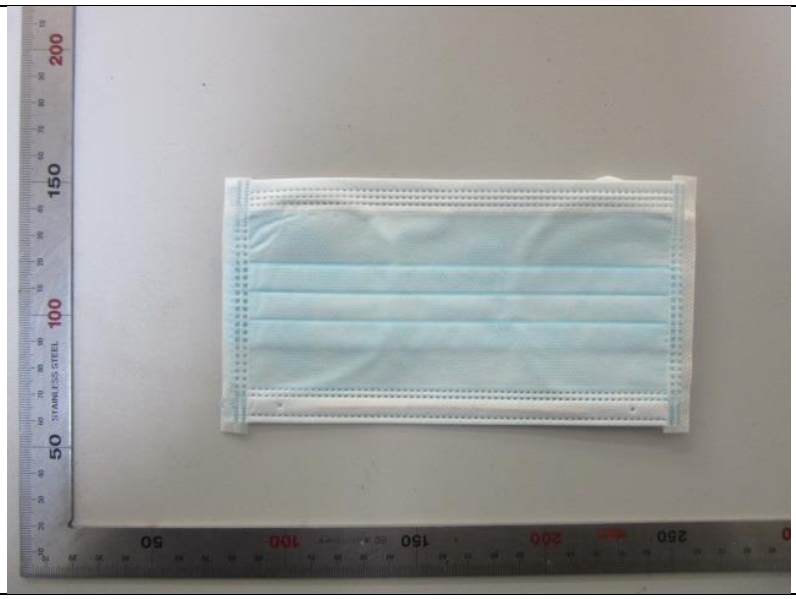
[ ] top

[ ] bottom



- End of Annex I -