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1	Technical Construction File
	EN 14683: 2019
Medical face r	nasks - Requirements and test methods
Report reference No:	TMSC20030321899
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Date of issue:	
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Standard	🛛 EN 14683: 2019
Review Report Form No	14683
TRF originator	GTS
Master TRF:	Reference No. EN 14683: 2019
Review procedure	GTS
Type of Review object	Medical masks
Trademark	•
Main Model:	A1
Other Models:	A. B.A2. A3, B1, B2, B3
Rating:	CE



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Possible review case verdicts:	
- review case does not apply to the test ob	ject 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 append	led to the report.
"(see appended table)" refers to a table ap	pended to the report.
Throughout this report a comma is used a	s the decimal separator.
The review results presented in this report	relate only to the object reviewed.
This report shall not be reproduced except	t in full without the written approval of the third party.
Testing:	
Date of receipt of review item:	February 25,2020
Date(s) of performance of review.	February 25.2020 to March 04.2020
General product information: Medical masks	
Summary of reviewing:	
This review report includes:	
Annex I: 4 page(s) of photo documentatio	ח.
Copy of marking plate	
Medical masks.	Marking
Model A1	







	Page 3 of 5 TMSC20030	321888 **	laking it easy:
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.	Туре I	P
5	Requirements		
5.1	General		
5.1.1	Materials and construction		
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness.		P
5.1.2	Design		
	The medical face mask shall have a means by which it can be fitted closely over the nosie, 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).		Ρ
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 face mask shall conform to the minimum value given for the relevant type in Table 1. For thick and rigid masks such as rigid duckbill or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE. When a mask consists of two or more areas with 	BFE ≥ 95	P
	different characteristics or different layer- composition, each panel or area shall be tested individually. The lowest performing panel or area shall determine the BFE value of the complete mask		
5.2.3	composition, each panel or area shall be tested individually. The lowest performing panel or area		





differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1. If the use of a respiratory protective device as face mask is required in an operating theate and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this European Standard. In such case, the device should fulfil the requirement as specified in the relevant Pressonal Protective Equipment (PPE) standard(s). 52.4 Splash resistance When tested in accordance with ISO 22809-2004 the resistance of the medical face mask to penetration of splashes of fiquid shall conform to the minimum value given for Type IIR in Table 1. N/A 5.2.5 Microb al cleanliness (Bioburden) Standard, In such case, the device standard in this European CPUIg tested (see Table 1). Type A comply with the requirement 5.2.5 Microb al cleanliness (Bioburden) When tested according to EN ISO 11737-1:2018. Type A comply with the requirement CPUIg tested (see Table 1). To determine the mask's bioburden according to EN ISO 11737-1:2018. refer to the procedure as described in Annex D. The number of masks that shall be tested is minimum 5 of the same batch/lot. Other test conditions as described in EN ISO 11737-1:2018. may be applied. In the test report. indicate the total bioburden per individual mask and based on the mask weight, the total bioburden per gram. P 5.2.6 Biocom	
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Microbial cleanliness ≤ 30 ≤ 30 ≤ 30	
(cfu/g) 5.30 5.30 * Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic isfutations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.	







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 face mask is supplied.	٩
	The following information shall be supplied: a) number of this European Standard;	
	b) type of mask (as indicated in Table 1).	
	c) EN ISO 15223-1:2018 and EN 1041:2008+A1:2013 should be considered.	

- End of Review Report -



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Type of equipment, model:

Medical masks , A1







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Photo documentation

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