



भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS

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व्यापक परिचालन मसौदा

प्रलेख प्रेषण संज्ञापन

हमारा संदर्भ	दिनांक
टी एक्स 36/टी-8	12-01-2012

तकनीकी समिति : चिकित्सीय (मेडटेक) अनुप्रयोगों के लिये तकनीकी वस्त्रादि,
विषय समिति, टी एक्स 36

प्राप्तकर्ता :

- 1 वस्त्रादि विभाग परिषद् (टी एक्स डी सी) के रुचि रखने वाले सदस्य
- 2 चिकित्सीय (मेडटेक) अनुप्रयोगों के लिये तकनीकी वस्त्रादि, विषय समिति, टी एक्स 36 के सभी सदस्य
- 3 रुचि रखने वाले अन्य निकाय

महोदय(यों),

निम्नलिखित प्रलेख संलग्न है :

- i) प्रलेख:टी एक्स 36(1040)
चिकित्सीय वस्त्रादि – प्रतिबैक्टीरिया कार्यकलापों के गुणात्मक निर्धारण की विधि
- ii) प्रलेख:टी एक्स 36(1041)
चिकित्सीय वस्त्रादि – प्रतिबैक्टीरिया कार्यकलापों के मात्रात्मक निर्धारण की विधि
- iii) प्रलेख:टी एक्स 36(1042)
चिकित्सीय वस्त्रादि – चेहरे के सर्जिकल नकाब के बैक्टीरिया निस्यन्दन दक्षता के मूल्यांकन की विधि

कृपया इस मानक मसौदो का अवलोकन करें और अपनी सम्मतियाँ यह बतातः हुए भजः कि यदि यह मसौदः राष्ट्रीय मानक का रूप में प्रकाशित हो जायें तो इन पर अमल करनः में आपको व्यवसाय अथवा कारोबार में क्या कठिनाइयाँ आ सकती हैं ।

सम्मतियाँ भजनः की अन्तिम तिथि: **15-04-2012**

सम्मतियाँ यदि कोई हो तो कृपया अधोहस्ताक्षरी को उपरलिखित पतः पर सलग्न प्रारूप में भजें ।

यदि कोई सम्मति प्राप्त नहीं होती हः अथवा सम्मति में कछल भाषा सखी त्रुटि हुई तो उपरोक्त प्रलख को यथावत अन्तिम रूप दः दिया जाएगा । यदि सम्मति तकनीकी प्रकृति की हुई तो विषय समिति का अध्यक्ष का परामर्श सः अथवा उनकी इच्छा पर आगः की कार्यवाही का लिए विषय समिति को भजः जानः का बाद प्रलख को अन्तिम रूप दः दिया जाएगा ।

यह प्रलख भारतीय मानक ब्यूरो की वबसाइट www.bis.org.in पर भी उपलब्ध हः

धन्यवाद ।

भवदीय

(अनिल कुमार)

वज्ञानिक ई एवः प्रमुख (वस्त्रादि)

सलग्न : उपरलिखित



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**DRAFT IN
WIDE CIRCULATION**

DOCUMENT DESPATCH ADVICE

Reference	Date
TX 36/T-8	12-01-2012

TECHNICAL COMMITTEE: TECHNICAL TEXTILES FOR MEDTECH APPLICATIONS
SECTIONAL COMMITTEE, TX 36

ADDRESSED TO :

1. Interested Members of Textiles Division Council, TXDC
2. All members of TX 36
3. All others interested

Dear Sir,

Please find enclosed the following document(s) :

- i) Doc:TX 36(1040) Medical textiles - Method for determination of antibacterial activity, Qualitatively
- ii) Doc:TX 36(1041) Medical textiles - Method for determination of antibacterial activity, Quantitatively
- iii) Doc:TX 36(1042) Medical textiles - Method for evaluation of the bacterial filtration efficiency of surgical face masks.

Kindly examine the draft standards and forward your views stating any difficulties which you are likely to experience in your business or profession, if these are finally adopted as National Standards.

Last Date for comments : **15-04-2012**

Comments if any, may please be made in the format as enclosed and mailed to the undersigned at the above address.

In case no comments are received or comments received are of editorial nature, you will kindly permit us to presume your approval for the above document as finalized. However, in case of comments of technical in nature are received then it may be finalized either in consultation with the Chairman, Sectional Committee or referred to the Sectional Committee for further necessary action if so desired by the Chairman, Sectional Committee.

The document is also hosted on BIS website www.bis.org.in.

Thanking you,

Yours faithfully,

(Anil Kumar)
Scientist E & Head (Textiles)

Encl: as above

FORMAT FOR SENDING COMMENTS ON BIS DOCUMENTS

(Please use A4 size sheet of paper only and type within fields indicated. Comments on each clause/subclause/table/fig etc. be started on a fresh box. Information in column 3 should include reasons for the comments and suggestions for modified working of the clauses when the existing text is found not acceptable. Adherence to this format facilitates Secretariat's work)

Please e-mail your comments to txd@bis.org.in or akbera@bis.org.in or Fax to 011 23231282

NAME OF THE COMMENTATOR/ORGANIZATION:

DOC. NUMBER AND TITLE:

Sl.No. (1)	Clause/Subclause/ Para No. (2)	Comments/suggestions (3)

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BUREAU OF INDIAN STANDARDS

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Doc: TX 36 (1042)

Draft Indian Standard

METHOD FOR EVALUATION OF THE BACTERIAL FILTRATION EFFICIENCY OF SURGICAL FACE MASKS

FOREWORD (Formal clauses shall be added later)

1 SCOPE

1.1 This standard prescribes a method for evaluation of the bacterial efficiency of the medical face mask materials, employing the ratio of the upstream bacterial challenge to downstream residual concentration to determine filtration efficiency of medical face mask materials.

2 TERMINOLOGY

2.1 For the purpose of this standard, the following definitions shall apply

2.1.1 Bacterial Filtration Efficiency

The effectiveness of a medical face mask material in preventing the passage of aerosolized bacteria; expressed in the percentage of a known quantity that does not pass the medical face mask at a given aerosol flow rate.

2.2.2 Bacterial Aerosol

A suspension of particles containing biological agents which have been dispersed in the gas.

3. PRINCIPLE

3.1 The fabric samples are clamped between a six- stage cascade impactor and an aerosol chamber. The bacteria aerosol is introduced into the aerosol chamber using a nebulizer and a culture suspension of staphylococcus aureus. The aerosol is drawn through the medical face mask material using a vacuum attached to the cascade impactor. The six stage cascade impactor uses six agar plates to collect aerosol droplets which penetrate the medical face mask material. Control samples are collected with no test specimen clamped in the test apparatus to determine the upstream aerosol counts.

3.2 The agar plates from the cascade impactor are incubated for 48 hours and counted to determine the number of viable particles collected. The ratio of the upstream counts to downstream counts collected for the test specimen are calculated and reported as present bacterial filtration efficiency.

4 APPARATUS

4.1 Autoclave

Capable of maintaining 121-123 °C.

4.2 Incubator

Capable of maintaining 37 ± 2 °C.

4.3 Analytical Balance

Capable of weighing 0.001 g.

4.4 Vortex Mixer

Capable of mixing the contents of 16 mm x 150 mm test tubes.

4.5 Orbital Shaker

Capable of achieving 100-250 rev per minutes.

4.6 Refrigerator

Capable of maintaining 2-8 °C.

4.7 Six stage viable particle cascade impactor.

4.8 Vacuum Pump

Capable of 57 litres per minute.

4.9 Air Pump/ Compressor

Capable of 1.1 kg/cm²

4.10 Peristaltic Pump

Capable of delivering 0.01 ml/minute.

4.11 Nebulizer

Capable of delivering mean particle size of 3.0 micrometer and a challenge level of 2200 particles per test.

4.12 Glass Aerosol Chamber

60 cm x 8 cm diameter tube.

4.13 Colony Counter

Manual or automatic, capable of counting upto 400 colonies per plate.

4.14 Automatic Pipetor

Capable of delivering 1.0 ± 0.05 ml.

4.15 Flow Meters

Capable of 28.3 litres per minute.

4.16 Pressure Gauges

Capable of 35 ± 1 kPa.

4.17 Air Regulator

5 REAGENTS

5.1 Staphylococcus aureus, ATCC#6358

5.2 Tryptic soy Agar (TSA) 6

5.3 Tryptic soy broth (TSB) 6

5.4 Peptone Water

6 MEDIA PREPARATION

6.1 Prepare media using standard microbiological techniques.

6.2 Prepare agar plates for cascade impactor as specified by the manufacturer of each cascade impactor.

7 SPECIMEN

7.1 Test specimens shall be taken from manufactured medical face masks, with all layers arranged in proper order.

8 CONDITIONING OF THE TEST SPECIMENS

8.1 Condition each test specimen for a minimum of 4 hours by exposure to a temperature 21 ± 5 °C and relative humidity 85 ± 5 percent.

9 PREPARATION OF THE BACTERIAL CHALLENGE

9.1 Inoculate an appropriate volume of tryptic soy broth with and incubate with mild shaking at 37 ± 2 °C for 24 ± 2 hours.

9.2 Dilute the culture in peptone water to achieve a concentration of approximately 5×10^5 CFU/ml.

9.3 The challenge delivery rate will be maintained at 2200 ± 500 viable particles per test.

10 PROCEDURE

10.1 Deliver the challenge to the nebulizer using a peristaltic pump. Connect tubing to nebulizer and peristaltic pump and into the challenge suspension; purge tubing and nebulizer of air bubbles.

10.2 Perform positive control run without a test specimen clamped into the test system to determine the number of viable aerosol particles being generated. The mean particle size of the aerosol will be calculated from the results of these positive control plates. Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediately begin sampling the aerosol using the cascade impactor. Adjust the flow rate through cascade impactor to 28.3 litres per minute.

10.3 Time the challenge suspension to be delivered to the nebulizer for one minute. Time the air pressure and cascade impactor to run for two minutes. At the conclusion of the positive control run, remove plates from the cascade impactor. Label each plate with the corresponding stage number.

10.4 Place the new agar plates into the cascade impactor and clamp the test specimen into the top of the cascade impactor with either the inside or outside oriented toward the challenge as intended.

10.5 Initiate the aerosol challenge as outlined above. Repeat the challenge procedure for each test specimen. Repeat a positive control sample after completion of the test sample test. Perform a negative control sample by collecting a two minute samples of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control sample.

10.6 Incubate the agar plates at 37 ± 2 °C for 48 hours. Count each of the six agar plates for the test specimens and positive controls, as specified by the manufacturer of the cascade impactor.

10.7 The filtration efficiency is calculated by

$$C - T/C \times 100$$

C – Average plate count total for test controls

T – Plate count total for test sample

11 REPORT

11.1 Bacterial filtration efficiency in percentage.