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व्यापक परिचालन मसौदा
चिकित्सीय वस्त्रादि — बिना बुने हुए जालीदार फोहे — विशिष्टि

Wide Circulation Draft

Medical Textiles — Nonwoven Gauze Swab— Specification

ICS: 11.040.30; 59.080.01

Technical Textiles for Medtech Applications Sectional Committee, TXD 36

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FOREWORD

(*Formal clauses will be added later*)

Nonwoven gauze swabs are widely used in healthcare settings for wound care, surgical procedures, and general medical treatments. They are particularly effective in wound cleaning and dressing general healthcare and first aid for managing minor procedures, minor cuts, abrasions, burns, or small surgical incisions. Their high absorbency allows them to effectively soak up blood, exudate, and other fluids, keeping the wound dry and promoting healing.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1 SCOPE

This standard specifies the performance requirement of nonwoven gauze swab (sterile and non — sterile) for single use intended for medical purpose. Non-woven gauze swab shall be used for general healthcare application and cleaning of outer surface of wound/skin during and post-surgery.

2 REFERENCES

The standards listed in Annex A contain provisions, which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated in Annex A.

3 TERMINOLOGY

For the purpose of this standard, the following term shall apply.

3.1 Manufacturer — Natural or legal person with responsibility for the processing of raw material or inputs in any manner that results in the emergence of a new product having a distinct name, character and use.

3.2 Nonwoven Gauze Swab — It is of mesh structure made from viscose (rayon) and polyester staple fibers blended spun lace nonwoven fabric with minimum 20 percent viscose (rayon) content.

3.3 Single-use Product — Product intended by the manufacturer to be used only once.

4 MATERIALS

The non-woven gauze swab (spunlace or spunbond or combination of both) shall be manufactured from cotton or viscose or blends of cotton, viscose, bamboo, polyester and polypropylene fibres. The product shall contain at least 20 percent of cotton or/and viscose fibre.

5 WORKMANSHIP AND FINISH

5.1 The nonwoven gauze swab shall be clean and free from substances liable to cause tendering during storage. The product shall be free from toxic or harmful substances.

5.2 The manufacture and preparation of the non-woven gauze swab shall be conducted under proper hygienic conditions.

6 REQUIREMENTS

The non-woven gauze swab shall conform to the requirements specified in Table 1.

Table 1 Performance Requirements for Nonwoven Gauze

(*Clause* 5)

Sl. No.	Characteristic	Requirement	Method of Test, Ref to

(1)	(2)	(3)	(4)
i)	Length and width, mm	As agreed to between the buyer and the seller with a tolerance of ± 1 mm	-
ii)	Fibre identification	At least 20 percent of cotton or/and viscose /absorbent fibres	IS 667/IS 3416
iii)	Weight per square metre, g/m^2, *Min*	30	IS 15891 (Part 1)
iv)	Absorbency (with distilled water) a) Liquid absorption time, s, *Max* b) Liquid absorptive capacity, percent, *Min*	 10 400	IS 15891 (Part 6)
v)	Tensile strength in machine direction (Dry) in N/5cm, *Min*	20	IS 15891 (Part 3)
vi)	Tensile strength in machine direction (Wet) in N/5cm, *Min*	20	IS 15891 (Part 3))
vii)	Cleanliness–Microbial/Bioburden Test (cfu/g), *Max* (in case of non-sterile)	100	IS/ISO 11737 Part 1
viii)	Cleanliness–Microbial/Bioburden Test (cfu/g), *Max* (sterile)	No viable microorganism shall be present'	IS/ISO 11737 Part 1
ix)	*p*H value of aqueous extract	5.5 to 8.0	IS 1390
x)	Water soluble substance, percentage, *Max*	1	IS 14944
xi)	Ether soluble substance percentage, *Max*	1	IS 14944
xii)	Particle release [log10 (lint count)]	≤ 4.0	IS 15891 (Part 10)
viii)	Freedom from optical whitener	No fluorescence or not more than occasional point of	Viewing under ultra-violet light

		fluorescence visible' when viewed under the ultra-violet (UV) light of wavelength 365 nm	
xiii)	Biocompatibility Evaluation Test **(*see* Note)		
	a) Cytotoxicity	Non- cytotoxic	IS/ISO 10993 Part 5 IS/ISO 10993 Part 12
	b) Irritation	Non- irritant	IS 17932 (Part 7)
	c) Skin sensitization	Non - sensitizer	IS 17932 (Part 6)

Note – Confirm the biocompatibility of raw material at designed stage. The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply for manufacturing the product

7 MARKING

7.1 Each pack of the nonwoven gauze swab shall be legibly and indelibly marked with following information:

a) Name of the product;
b) Length and width of the product;
c) Number of gauze swab in a packet;
d) Manufacturer's name, initials or trademark, if any;
e) Month and year of manufacture,
f) Batch/lot number;
g) Country of origin;
h) Instruction for use, storage and safe disposal;
i) Information on sterilized or unsterilized: and
j) Any other requirement as per Medical Device Rules, 2017 or as required by the law in force or as agreed between the buyer and the seller.

7.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the Bureau of Indian Standards Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark

8 SAMPLING AND CRITERIA FOR CONFORMITY

8.1 LOT

All the nonwoven gauze swab of the same material and dimensions produced under similar conditions of manufacture shall constitute a lot.

8.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

8.1.2 The number of packs of nonwoven gauze swab to be selected from the lot shall depend on the size of the lot and shall be in accordance with col 2, col 3 and col 5 of Table 2.

8.1.3 These nonwoven gauze swab shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

Table 2 Number of Nonwoven Gauze Swab to be selected
(*Clause* 8.1.2)

Sl No.	**Lot size**	**Non-destructive testing**		**Destructive testing**	
		No. of packs of nonwoven gauze to be selected	Acceptance Number	No. of packs of nonwoven gauze to be selected	Acceptance Number
(1)	N (2)	n (3)	a (4)	n1 (5)	a2 (6)
i)	Up to 280	13[1]	1	8	0
ii)	281 - 500	20	2	8	0
iii)	501 - 1200	32	3	13	0
iv)	1201 - 3200	50	5	13	0
v)	3201 - 10000	80	7	20	1
[1] Or lot size when less than 13					

8.2 Number of Tests and Criteria for Conformity

8.2.1 All nonwoven gauze swab selected as per column 3 of Table 2 shall be examined for manufacture, workmanship and finish.

8.2.1.1 Any nonwoven gauze swab failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 4 of Table 2. Otherwise, the lot shall be rejected.

8.2.2 Out of the sample already found satisfactory according to **6.2.1.1**, a sub-sample as per column 5 of Table 2 shall be taken. This sub-sample shall be further tested for the remaining requirements.

8.2.3 The lot shall be considered as conforming to the requirements of the specification, if the total number of defective gauze absorbent found in the sample (*see* **8.2.2**) is less than or equal to the acceptance number as given in col 6 of Table 2.

9 PACKING

The nonwoven gauze swab shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of the packing shall be as agreed to between the buyer and the seller. The wax paper shall not be used for any wrapping as it affects the absorbency of the gauze. If the material is sterilized, it shall be enclosed in a sealed package which is adequate to maintain the sterility of the material up to the time of opening the package. Packaging of the product should be such as to maintain the integrity of the product throughout its shelf life.

ANNEX A

(*Clause* **2**)

LIST OF REFERRED STANDARDS

IS No.	*Title*
IS 667 : 1981	Methods for identification of textile fibres (*first revision*)
IS 1390 : 2022/ISO 3071 : 2020	Textiles — Determination of *p*H of aqueous extract (*third revision*)
IS 14944 : 2020	Surgical dressings — Methods of test (*first revision*)
IS 3416 : 2024/ISO 1833-11 : 2017	Textiles — Quantitative chemical analysis — Mixtures of certain cellulose fibres with certain other fibres (method using sulphuric acid) (*third revision*)
IS 15891 (Part 1) :2011/ ISO 9073-1:1989	Textiles — Test methods for non-wovens Part 1 Determination of mass per unit area
IS 15891 (Part 3) : 2024/ ISO 9073-3 : 2023	Nonwovens — Methods of test Part 3 Determination of tensile strength and elongation at break using the strip method (*first revision*)
IS 15891 (Part 6) : 2012/ ISO 9073-6 : 2000	Textiles — Test methods for nonwovens Part 6 Absorption
IS 15891 (Part 10): 2017/ISO 9073-10: 2003	Textiles — Test methods for nonwovens: Part 10 Lint and other particles generation in dry state
IS 4905 : 2015	Random sampling and randomization procedures (*first revision*)
IS/ISO 11737-1 : 2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products

IS 17932 (Part 6) : 2023	Biological evaluation of medical devices Part 6 Tests for skin sensitization
IS 17932 (Part 7) : 2024	Biological evaluation of medical devices Part 7 Tests for irritation
IS/ISO 10993 (Part 5) : 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity
IS/ISO 10993-12 : 2021	Biological evaluation of medical devices: Part 12 Sample preparation and reference materials