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(Ministry of Consumer Affairs, Food & Public Distribution, Govt. of India)

Review Document Basic Details Sectional Committee No. & Title: MHD 1 - Surgical Instruments 1. 2. IS No : IS 4275 : 1967 Title : 3. Scissors, Kilner's for Plastic Surgery 4. Date of Previous Review: December, 2016

Review Analysis

5.1 Status of standard(s), if any from which assistance had been drawn in the formulation of this IS.					
S.No.	Standard (No.)	Standard (Title)	Whether the standard has since been revised	Major changes	Action proposed
1	IND/GS/MED/379(b)	Scissors, surgical Kilner's, 4 3/4 in., curved, blunt pointed, Directorate of Standardization, Dept. of Defence Production	Not available	-	-
2	IND/GS/MED/386(b)	Scissors, surgical (Kilner) straight, Directorate of Standardization, Dept. of Defence Production	Not available	-	-

5.2 Status of standard referred in the IS.						
S.No.	Referred standards (No.)	Referred standards (Title)	Since revised IS no. of the corresponding IS	Changes in the referred Standards since last review of IS	Changes in the referred standard which are affecting the standard under review	Action proposed
1	IS 7531:1975	Method for boiling and autoclaving test for corrosion resistance of stainless-steel surgical instruments.	IS 7531:1990 Surgical instruments - Corrosion resistance of stainless-steel surgical instruments - Methods of tests (First Revision) Revised, Current	Test for Corrosion Resistance	Test for Corrosion Resistance	Parallel Standard IS/ISO 7741: 1986 Instruments for Surgery â ^[2] Scissors and Shears â ^[2] General Requirements and Test Methods to be adopted.
2	IS 3642:1978	First Revision General requirements for surgical instruments	IS 3642: Part 1:1990/ ISO 7740: 1985 Surgical instruments - Specification: Part 1 non - Cutting, articulated instruments (Second Revision)	Shape and Dimension requirements	Shape and Dimension requirements	Parallel Standard IS/ISO 7741: 1986 Instruments for Surgery â ^[2] Scissors and Shears â ^[2] General Requirements and Test Methods to be adopted.
3	IS 1362-1962	Dimensions for screw threads for general purposes (diameter range 1�26 to 39 mm).	IS 4218: Part 1:2001/ ISO 68-1:1998 ISO general purpose metric screw threads: Part 1 basic profile - second revision)	Screw Requirements	Screw Requirements	Parallel Standard IS/ISO 7153-1 : 2016 Surgical Instruments â[?][?] Materials Part 1 Metals to be adopted.
4	IS 1570-1961	Schedules for wrought steels for general engineering purposes	Revised in several Parts IS 1570 (Part 1): 1978 Schedules for wrought steels: Part 1 steels specifed by tensile and/or yield properties (First Revision) IS 1570 (Part 2): 1979 Schedules for wrought steels: Part 2 carbon steels (Unalloyed Steels) IS 1570 (Part 2 / Sec 1): 1979 Schedules for wrought steels: Part 2 carbon steels (Unalloyed Steels): Sec 1 wrought products (Other Than Wires) with specified chemical composition and related properties (First Revision) IS 1570 (Part 2 / Sec 2): 1987 Schedules for wrought steels: Part 2 carbon steels (Unalloyed Steels): Sec 2 carbon steel wires with related properties (First Revision) IS 1570 (Part 3): 1979 Schedules for wrought steels: Part 3 carbon and carbon - Manganese free cutting steels (First Revision) IS 1570 (Part 4): 1988 Schedules for wrought steels: Part 4 alloy steels (Alloy Constructional and Spring Steels) with specified chemical composition and mechanical properties (First Revision) IS 1570 (Part 5): 1985 Schedules for wrought steels: Part 5 stainless and heat - Resisting steels (Second Revision) IS 1570 (Part 6): 1996 Schedules for wrought steels: Part 6 carbon and alloy tool steels Part 7 steels for elevated temperature service (Creep Resistant Steels)	Material Composition	Material Composition	Parallel Standard IS/ISO 7153-1 : 2016 Surgical Instruments â[2][2] Materials Part 1 Metals to be adopted.

S.No.	Standard (No.)	Standard (Title)	Provisions that could be relevant while reviewing the IS	Action proposed
	IS/ISO 7153-1:2016	Surgical Instruments â[2][2] Materials Part 1 Metals	Complete material requirements can be referred to this standard	Considering the comprehensive materia coverage of this standard, adoption and cross reference of same is recommended
2	IS/ISO 7741:1986	Instruments for Surgery â[2][2] Scissors and Shears â[2][2] General Requirements and Test Methods	All generic tests can be referred to this standard.	Considering the comprehensive test coverage of this standard, adoption and cross reference of same is recommended

5.4 Technical comments on the standard received, if any.						
S.No.	Source	Clause of IS	Comment	Action proposed		
No entry made in this table						

5.5 Information available on relevant technical developments					
S.No.	Source	Development	Relevant clause of the IS under review that is likely to be impacted (Clause & IS No.)	Action proposed	
1	General	New materials added	Cl 2 of IS 4275	IS/ISO 7153-1:2016 Surgical Instruments â 22 Materials Part 1 Metals Considering the comprehensive material coverage of this standard, adoption and cross reference of same is recommended.	
2	General	Testing procedures updated.	Cl 6 of IS 4275	IS/ISO 7741:1986 Instruments for Surgery â ^[2] Scissors and Shears â ^[2] General Requirements and Test Methods Considering the comprehensive test coverage of this standard, adoption and cross reference of same is recommended.	

5.No.	Related IS (revised or new)	Related IS Title	Provision in the IS under review that would be impacted & the clause no. or addition of new clause/provision	Changes that may be necessary in the Standards under review	Action proposed
L	IS/ISO 7153 : Part 1-2016	Surgical instruments - Materials: Part 1 metals	Cl 2 of IS 4275	Considering the comprehensive material coverage of this standard, adoption and cross reference of same is recommended.	Considering the comprehensive material coverage of this standard, adoption and cross reference of same is recommended.
2	IS/ISO 7741 -1986	Instruments for surgery - Scissors and shears - General requirements and test methods	Cl 6 of IS 4275	Considering the comprehensive material coverage of this standard, adoption and cross reference of same is recommended	Considering the comprehensive material coverage of this standard, adoption and cross reference of same is recommended

5.7 Any consequential changes to be considered in other IS.					
S.No.	Related IS to get impacted	Related IS Title	Requirements to be impacted		
1	IS 4275-1967	Scissors, Kilner's for Plastic Surgery	Cl 2 and Cl 6		

Other	Other Details					
6.	Any other observation:		The standard under review i.e IS 4275: 1967 Scissors, Kilner's for Plastic Surgery is a surgical instrument used in various general surgeries as well as super specialty surgeries. Usually the surgical instruments are procured as a set by the respective departments (Example: Gen. Surgery, Cardio-Thoracic Surgery, Plastic Surgery, etc.,) in a hospital. While the metallic material requirements of most of the instruments are usually similar, the design or shapes and sizes vary. During the setup of any surgical facility, the medical team has to go through a lot of listing work selecting the surgical instruments required referring various brochures / catalogues of manufacturers. The task is repeated at every institution. Taking the current standard under review as an example, MHD has 30 standards related to various types of scissors. Most of these standards have same material and testing requirements with the only difference being the design of the scissor. Considering the governmental focus on developing public healthcare system by establishing new institutions and upgrading the existing institutions, it is recommended to create comprehensive Medical Department specific standards for surgical instruments with proper basic listing of instruments and their designs included in the parent standard or cross referred to secondary standard. This would help the Govt. institutions in faster establishment of facilities and also guide the manufacturers in maintaining department specific products readily available.			
7.	Upload Supporting Document(s)					
7.1	ARP Report	<u>64_10906_220731114100</u>	_ARP_Report.docx			
7.2	7.2 Draft Document <u>64_10900</u>		Draft_Document.docx			
8.	Recommendations - On the basis of the analysis of the info available as mentioned above consideration of sectional committee is solicited on the following aspects of the IS under review:		In the above context it is proposed update the Cl 2 and Cl 6 of the standard under review with the cross reference to the parallel standards as mentioned above. Further it is also proposed to put up the remarks for consolidation of the surgical instrument related standards in the next meeting of the related technical committee for their opinion. The surgical instrument standards may be considered for consolidation as a surgical department specific set or a depending upon a type of instrument. For example, all the scissors used in surgery can be consolidated as single standard or all the metallic surgical instruments used in a specific surgical department may be considered for consolidation as a single standard for easy reference.			