



Review Document

Basic Details

1.	Sectional Committee No. & Title:	MHD 1 - Surgical Instruments
2.	IS No :	IS 4085 : 1967
3.	Title :	Specification for knives, amputating
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
No entry made in this table					

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 3318: 1965	General Requirements of Surgical Scalpels and Knives	Under Review			
2	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	Inclusion of copper sulphate test for corrosion resistance on stainless steel surgical instruments.		Refer to revised current Standard
3	IS 1068: 1958	Specification for copper nickel and chromium electroplated coatings	IS 1068:1993/ ISO 1456 Electroplated coatings of nickel plus chromium and copper plus nickel plus chromium - Specification (Third Revision) Revised and Current	Changes in plating		Refer to revised current Standard

5.3 Any other standards available related to the subject & scope of the standard being reviewed (International/regional/other national/association/consortia, etc or of new or revision of existing Indian Standard).

S.No.	Standard (No.)	Standard (Title)	Provisions that could be relevant while reviewing the IS	Action proposed
No entry made in this table				

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
No entry made in this table				

5.6 Issues arising out of changes in any related IS or due to formulation of new Indian Standard.

S.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
No entry made in this table					

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
No entry made in this table			

Other Details

6.	Any other observation:	
7.	Upload Supporting Document(s)	

7.1 ARP Report	IS_4085.docx
7.2 Draft Document	No Document Uploaded

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:	<div style="border: 1px solid black; padding: 5px;"> It is recommended to revise the standard considering the changes in the Material Characteristics (Composition, Hardness, Finishing, Corrosion resistance), Performance testing, Sterilization Packaging and Sampling Criteria </div>
----	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------