



भारतीय मानक ब्यूरो

(उपभोक्ता मामले, खाद्य एवं सार्वजनिक वितरण मंत्रालय, भारत सरकार)

BUREAU OF INDIAN STANDARDS

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

मानक भवन, 9 बहादुरशाह जफर मार्ग नई, दिल्ली-110002

Manak Bhavan ,9 Bahadur Shah Zafar Marg, New Delhi-110002

Phones: 23230131 / 23233375 / 23239402

Website: www.bis.org.in , www.bis.gov.in

Review Document

Basic Details

1.	Sectional Committee No. & Title:	MHD 1 - Surgical Instruments
2.	IS No :	IS 3318 : 1965
3.	Title :	General requirements for surgical scalpels and knives
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	B.S. 2982: 1958	Scalpel with detachable blades. British Standards Institution.	BS 2982:1992 Specification for materials and packaging of surgical scalpels with detachable blades Revised and Current	Change in the material of the blade	Already covered by IS 3319:1995 Blades, surgical, detachable (Bard Parker Type) and handles
2	BS BS 2820:1957	Specification Surgical scalpels	Withdrawn	Withdrawn	Product obsolete

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 1570 : Part 1 : 1978	Schedules for wrought steels: Part 1 steels specified by tensile and/or yield properties (First Revision)	IS 1570: Part 1:1978 Schedules for wrought steels: Part 1 steels specified by tensile and/or yield properties (First Revision) Revised and Current	Changes in the Composition of Blade and Handle Material	Amended in 1981 and Reaffirmed in 2019	Revised Version of the Standard to be referred in the revision
2	IS 2451 : 1994	Copper alloys - Nickel silver - Ingots and castings - Specification (First Revision)	IS 2451:1994 Copper alloys - Nickel silver - Ingots and castings - Specification (First Revision) Revised and Current	Changes in the Composition of Handle Material	Reaffirmed in 2021	Revised Version of the Standard to be referred in the revision
3	IS 291 : 1989	Naval brass rods and sections for machining purposes - Specification (Third Revision)	IS 291:1989 Naval brass rods and sections for machining purposes - Specification (Third Revision) Revised and Current	Changes in the Composition of Handle Material	Reaffirmed in 2021	Revised Version of the Standard to be referred in the revision
4	IS 1068 : 1993	Electroplated coatings of nickel plus chromium and copper plus nickel plus chromium - Specification (Third Revision)	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 the Composition of Plating on Handle	Reaffirmed in 2021	Revised Version of the Standard to be referred in the revision

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
1	ISO 7740:1985	Instruments for surgery — Scalpels with detachable blades — Fitting dimensions	Pertains to and already covered by IS 3319:1995	Irrelevant with IS 3318:1965
2	IS 3319 : 1995	Blades, surgical, detachable (Bard Parker Type) and handles - Specification (Fourth Revision)	All the market relevant aspects of IS 3318:1965 were sufficiently covered by this IS	IS 3318 recommended to be withdrawn
3	DIN 58849-2: 2010	Medical Instruments - Scalpel Handles for Detachable Blades - Part 2: Handles	Pertains to and already covered by IS 3319:1995	Irrelevant with IS 3318:1965

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	BIS Licensee	Product obsolete in market	Product as per IS 3318:1965 are obsolete in market. All aspects of this standard are already covered by IS 3319:1995	Withdrawal of IS 3318:1965

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
1	IS 3319-1995	Blades, surgical, detachable (Bard Parker Type) and handles - Specification (Fourth Revision)	This IS after revision covers all the relevant aspects of IS 3318 :1965	Nil	Reaffirm IS 3319 after review and withdraw IS 3318

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 3319-1995	Blades, surgical, detachable (Bard Parker Type) and handles - Specification (Fourth Revision)	Although the products as per IS 3318:1965 are obsolete in market, the material as per Cl 2.5 and types of handles as per Cl 4.1 may be incorporated as separate varieties in IS 3319:1995

Other Details	
6.	<p>Any other observation:</p> <p>The Indian Standard IS 3318: 1965 General requirements for surgical scalpels and knives was developed as a grouped standard in series along with IS 3319:1965 Surgical scalpels with detachable blades and IS 3320:1965 Surgical scalpels. The standard was developed with assistance from B.S. 2820: 1957 Surgical scalpels and B.S. 2982: 1958 Scalpel with detachable blades. The IS 3319:1965 Surgical scalpels with detachable blades has been revised to IS 3319: 1995 Blades, surgical, detachable (Bard Parker Type) and handles - Specification (Fourth Revision). As on date there are eight licences operation as per IS 3319:1995 and none as per IS 3318: 1965 and IS 3320:1973. M/s Paramount Surgimed Limited, a BIS Licensee for IS 3319:1995 from Rajasthan is a reputed manufacturer and exporter of surgical scalpels. M/s Paramount Surgimed Ltd. was contacted for feedback on review of IS 3318:1965. After a detailed discussion and further analysis of IS series 3318, 3319 3320 it was understood that the market requirements of Surgical Scalpels were sufficiently incorporated in the latest version of IS 3319:1995. Secondly the usage of fixed blade scalpels has become outdated and obsolete owing to the reason of cross contamination, ease of use provided by the detachable blades and cumbersome process of re-sharpening. Accordingly, all the licenses are running on IS 3319:1995 whereas there are no licenses on IS 3318 and IS 3320. Further, BS 2820:1957 Specification Surgical scalpels has been withdrawn whereas B.S. 2982: 1958 Scalpel with detachable blades has been revised to BS 2982:1992 Specification for materials and packaging of surgical scalpels with detachable blades.</p>
7.	Upload Supporting Document(s)
7.1 ARP Report	Review Analysis IS 3318.docx
7.2 Draft Document	Draft.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:	<p>As the fixed blade or single body scalpels have become obsolete in the market for surgical purposes and IS 3319:1995 sufficiently covering the detachable blade aspects, it is therefore recommended for withdrawal of IS 3318:1965. Although the products as per IS 3318:1965 are obsolete in market, the material as per Cl 2.5 and types of handles as per Cl 4.1 may be incorporated as separate varieties in IS 3319:1995</p>
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