Draft for Public Comment

Form 36

DPC: 24/30484674 DC

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Date: 19 November 2024
Origin: International

Latest date for receipt of comments: 12 January 2025

Project No. 2023/03005

Responsible committee: CH/150/1 Materials for surgical implants

Interested committees:

Title: Draft BS ISO 5834-2 Implants for surgery - Ultra-high-molecular-weight polyethylene. Part 2: Moulded forms.
Please notify admin.start@bsigroup.com if you are aware of any keywords that might assist in clarifying or identifying the standard or of the content of this standard: i) has any issues related to 3rd party IPR, patent or copyright ii) affects other national standard(s) iii) requires additional national guidance or information

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at **https://standardsdevelopment.bsigroup.com/**. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex **(e.g. 3.1)**	Paragraph/ Figure/Table/Note	**Type of comment**	**Commend (justification for change) by the MB**	**Proposed change by the MB**	**Secretariat observations on each comment submitted**
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

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DRAFT International Standard

ISO/DIS 5834-2

ISO/TC **150**/SC **1**

Secretariat: **DIN**

Voting begins on:
2024-11-19

Voting terminates on:
2025-02-11

Implants for surgery — Ultra-high-molecular-weight polyethylene —

Part 2: Moulded forms

Implants chirurgicaux — Polyéthylène à très haute masse moléculaire —

Partie 2: Produits sous forme moulée

ICS: 11.040.40

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Reference number
ISO/DIS 5834-2:2024(en)

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