

BS EN ISO 7439:2011



BSI Standards Publication

Copper-bearing contraceptive intrauterine devices — Requirements and tests (ISO 7439:2011)

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National foreword

This British Standard is the UK implementation of EN ISO 7439:2011. It supersedes BS EN ISO 7439:2009 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/157, Mechanical contraceptives.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 August 2011.

Amendments issued since publication

Date	Text affected
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English Version

Copper-bearing contraceptive intrauterine devices - Requirements and tests (ISO 7439:2011)

Dispositifs intra-utérins contenant du cuivre - Exigences,
essais (ISO 7439:2011)

Kupferhaltige Intrauterinpessare zur Empfängnisverhütung
- Anforderungen, Prüfungen (ISO 7439:2011)

This European Standard was approved by CEN on 31 May 2011.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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Foreword

This document (EN ISO 7439:2011) has been prepared by Technical Committee ISO/TC 157 "Non-systemic contraceptives and STI barrier prophylactics" in collaboration with Technical Committee CEN/TC 285 "Non-active surgical implants" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2011, and conflicting national standards shall be withdrawn at the latest by December 2011.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 7439:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 7439:2011 has been approved by CEN as a EN ISO 7439:2011 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA — Correspondence between this International Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	1, 2, 3, 4, 6	refers to 1st indent of ER 1
5.1	1, 2, 3, 4	refers to 1st indent of ER 1
5.2	1, 2, 9.2	refers to 1st indent of ER 1
5.3.1	1, 2, 9.2	refers to 1st indent of ER 1
5.3.2	3, 4	
5.3.3	1, 2	refers to 1st indent of ER 1
5.3.4	1, 2, 9.2	refers to 1st indent of ER 1
5.4	9.2, 12.7.1	
5.5.1	5	
5.5.2	4	
5.6	4	
5.7	3, 4	
6	7.1, 7.2, 8.1	
7.1	1, 2, 3, 4, 6, 8.1	refers to 1st indent of ER 1
7.6	2, 7.1, 7.2, 7.5	
7.7	1, 2, 3, 4, 6, 6.a	refers to 1st indent of ER 1
8	1, 2, 3, 4, 7.1, 7.2	refers to 1st indent of ER 1

9	8.3, 8.4, 8.5	
10	5, 8.3, 8.6	
11.1	13.1, 13.2	
11.2	13.3 a), 13.3 c) to f), 13.3 m)	The part of ER 13.3.a) relating to the information on the authorized representative is not addressed in this International Standard.
11.3	13.3 a), 13.3 d) to f)	The part of ER 13.3.a) relating to the information on the authorized representative is not addressed in this International Standard.
11.4	13.3 a) and 13.3 b), 13.3 k), 13.6 b), 13.6 e) and 13.6 f), 13.6 k), 13.6.l)	The part of ER 13.3.a) relating to the information on the authorized representative is not addressed in this International Standard.
11.5	13.4, 13.6 a) and 13.6 b), 13.6 d), 13.6.e), 13.6 i), 13.6 k) to n)	
		ER 13.3.f) is only partly addressed: safety issues. 13.6 h) is not addressed in this International Standard. 13.6 q) is not addressed in this International Standard.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Contents

Page

Foreword	iv
Introduction.....	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Intended performance.....	2
5 Design attributes	2
6 Materials	4
7 Design evaluation	4
8 Manufacturing and inspection	8
9 Sterilization	8
10 Packaging.....	8
11 Information to be supplied by the manufacturer	8
Bibliography.....	11

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 7439 was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

This second edition¹⁾ cancels and replaces the first edition (ISO 7439:2002), of which it constitutes a minor revision.

1) ISO 7439:2002 was incorrectly given as being the “second” edition, but as it replaced a Technical Report, ISO/TR 7439:1981, as such it was the *first* edition as an International Standard.