



BSI Standards Publication

Copper-bearing contraceptive intrauterine devices — Requirements and tests

National foreword

This British Standard is the UK implementation of EN ISO 7439:2023. It is identical to ISO 7439:2023. It supersedes BS EN ISO 7439:2015, which is withdrawn.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 committee manager.

BSI, as a member of CEN, is obliged to publish EN ISO 7439:2023 as a British Standard. However, attention is drawn to the fact that during the development of this European Standard, the UK committee voted against its approval as a European Standard.

The UK committee voted against the draft standard at both the Enquiry (DIS) stage and the Approval (FDIS/Formal Vote) stage. The UK committee's technical reasons for voting against the standard are as follows.

- a) They noted that the final paragraph of the Introduction does not make it clear that an IUD is implanted in the uterus for a specified period of time.
- b) In the definition of “thread” (3.3), the interpretation of the term “professional” varies between different cultures and the committee believes “trained” is a clearer description.
- c) The committee believes the definition of “client” (3.7) could be more inclusive and encompassing by using the definition “person/patient receiving counselling and being fitted with a copper-bearing IUD”.
- d) The committee believes the reference to an “IUD still in situ” (5.2.8 b)) may cause confusion and could be more specific: when inserted, an IUD is “in utero” and the committee recommends users keep this expression in mind throughout (see also 12.4 and 12.5).
- e) The committee believes the term “the client” should be used consistently in relation to the information to be supplied by the manufacturer (12.4, 12.5 and 12.6), in place of “the woman” to be more inclusive and consistent.
- f) The committee notes that the advice regarding condom use in the Introduction would be helpful if included in the information to be supplied by the manufacturer that is intended for the client (12.5 b)).
- g) The committee points out that in order to most effectively help the client, the example of an IUD reminder card (12.6, figure 1) should include contact information for the facility that will deal with problems and questions: i.e. telephone number, postal address and, if available, website.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.