



# SLOVENSKI STANDARD SIST EN ISO 7439:2023

01-september-2023

Nadomešča:  
SIST EN ISO 7439:2015

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**Intrauterini kontracepcijski pripomočki z bakrenim nosilcem - Zahteve in preskusi (ISO 7439:2023)**

Copper-bearing contraceptive intrauterine devices - Requirements and tests (ISO 7439:2023)

Kupferhaltige Intrauterinpressare zur Empfängnisverhütung - Anforderungen und Prüfungen (ISO 7439:2023)

Dispositifs contraceptifs intra-utérins contenant du cuivre - Exigences et essais (ISO 7439:2023)

**Ta slovenski standard je istoveten z: EN ISO 7439:2023**

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**ICS:**

11.200	Načrtovanje družine. Mehanski kontracepcijski pripomočki	Birth control. Mechanical contraceptives
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**SIST EN ISO 7439:2023**

**en,fr,de**



EUROPEAN STANDARD

EN ISO 7439

NORME EUROPÉENNE

EUROPÄISCHE NORM

April 2023

ICS 11.200

Supersedes EN ISO 7439:2015

English Version

## Copper-bearing contraceptive intrauterine devices - Requirements and tests (ISO 7439:2023)

Dispositifs contraceptifs intra-utérins contenant du  
cuivre - Exigences et essais (ISO 7439:2023)

Kupferhaltige Intrauterinpessare zur  
Empfängnisverhütung - Anforderungen und Prüfungen  
(ISO 7439:2023)

This European Standard was approved by CEN on 22 January 2023.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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## European foreword

This document (EN ISO 7439:2023) 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of an identical text or by endorsement, at the latest by October 2023, and conflicting national standards shall be withdrawn at the latest by October 2023.

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

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2023-04

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**Copper-bearing contraceptive  
intrauterine devices — Requirements  
and tests**

*Dispositifs contraceptifs intra-utérins contenant du cuivre —  
Exigences et essais*

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## Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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This document was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 7439:2015), which has been technically revised.

The main changes are as follows:

- the subclause on clinical performance has been revised (see [5.2](#));
- the movable collar has been added in the subclause on insertion instrument (see [6.3.4](#));
- requirements for packaging integrity have been added;
- the instructions for health care providers have been amended in accordance with the "Family planning: A global handbook for providers"<sup>[4]</sup>;
- the requirement for stability in situ has been removed since there is no practical way of controlling it.

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