ISO 7439:2023-04 (E)

Copper-bearing contraceptive intrauterine devices - Requirements and tests

Contents

Page

Foreword v

Introduction vi

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 Qualityverification 2

5 Intended clinical performance 3
5.1 General 3
5.2 Clinical performance 3
5.2.1 General 3
5.2.2 Study duration 3
5.2.3 Study population 3
5.2.4 Sample size 4
5.2.5 Contraceptive performance 4
5.2.6 Expulsion rate 4
5.2.7 Discontinuation rate 4
5.2.8 Investigation report 4
5.2.9 Labelling 5

6 Design attributes 5
6.1 General 5
6.2 Shape 6
6.3 Dimensions 6
6.3.1 IUD 6
6.3.2 Copper components 6
6.3.3 Thread 6
6.3.4 Insertion instrument 6
6.4 Tensile force 6
6.5 Stability 7
6.5.1 Shelf-life stability 7
6.6 Viscoelastic property 7
6.7 Detection by X-ray 7

7 Materials 7

8 Design evaluation 7
8.1 General 7
8.2 Determination of dimensions 8
8.3 Determination of tensile force 8
8.3.1 Principle 8
8.3.2 Apparatus 8
8.3.3 Procedure 8
8.3.4 Test report 8
8.4 Test of elastic recovery (memory test) 9
8.4.1 Principle 9
8.4.2 Procedure 9

8.4.3 Test report 9
8.5 Determination of barium sulfate content and identification of barium and sulfate 9
8.5.1 Ash content test 9
8.5.2 Identity test 9
8.6 Pre-clinical evaluation 9

9 Manufacturing and inspection 10

10 Sterilization 10

11 Packaging 10

12 Information to be supplied by the manufacturer 10
12.1 General 10
12.2 Labelling of the primary container 11
12.3 Labelling of the secondary container 11
12.4 Instructions for the health care providers 11
12.5 Information intended for the client after insertion of the IUD 12
12.6 Written information intended for the client 13

Annex A (normative) Sampling requirements for testing copper bearing IUDs 14

Bibliography 16