

### Contents

	Foreword	
	Introduction	
1	Scope	
2	Normative references	
3	Terms and definitions	
4	Requirements	
4.1	Quality verification	
4.2	Physical requirements	
4.2.1	Dimensions	
4.2.2	Tensile properties	
4.2.3	Loading force on ring applicator	
4.2.4	Elastic memory	
4.2.5	Repeat loading strength	
4.2.6	Visible defects	
4.3	Packaging	
4.3.1	Packing mode	
4.3.2	Primary pouch	
4.3.3	Instruction for use	
4.3.4	Package seal strength	
4.3.5	Package seal integrity	
4.3.6	Sterility	
4.4	Biological requirements	
4.5	Radio-opacity	
4.6	Clinical evaluation	
4.6.1	General	
4.6.2	New clinical study of manufacturer's fallopian rings	
5	Storage condition	
6	Labelling	
7	Shelf life	
7.1	General	
7.2	Procedure for determining shelf life by real-time stability studies	
7.3	Procedure for determining shelf life by accelerated stability studies	
Annex A	(normative) Sampling plan and acceptance criteria for a continuing series of lot	
Annex B	(informative) Sampling plans intended for assessing compliance of isolated lots	
Annex C	(normative) Determination of dimensions	
C.1	General	
C.2	Apparatus	
C.3	Procedure	
Annex D	(normative) Determination of tensile properties	
D.1	General	
D.2	Apparatus	
D.3	Procedure	

**Annex E (normative) Determination of loading force on ring applicator**

- E.1 General**
- E.2 Apparatus**
- E.3 Universal testing machine (UTM)**
- E.4 Procedure**

**Annex F (normative) Determination of elastic memory**

- F.1 General**
- F.2 Apparatus**
- F.3 Procedure**

**Annex G (normative) Determination of repeat loading strength**

- G.1 General**
- G.2 Apparatus**
- G.3 Procedure**

**Annex H (normative) Determination of shelf life by real time stability study**

- H.1 General**
- H.2 Apparatus**
- H.3 Procedure**
- H.4 Test method**
- H.5 Test report**

**Annex I (normative) Determination of shelf life by accelerated stability study**

- I.1 General**
- I.2 Apparatus**
- I.3 Procedure**
- I.4 Test method**

**Annex J (normative) Package seal integrity and seal strength**

- J.1 General**
- J.2 Apparatus**
- J.3 Procedure**
  - J.3.1 Package seal strength**
  - J.3.2 Package seal integrity**

**Annex K (normative) Reporting of test results**

**Page count: 27**