

ISO 25841:2017-08 (E)

Female condoms - Requirements and test methods

Contents		Page
Foreword		v
Introduction		vii
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Quality verification	5
5	Lot size	6
6	Design	6
6.1	General	6
6.2	Product insertion feature	6
6.3	Retention features	7
6.4	Lubrication	7
6.5	Dimensions	8
6.5.1	Length	8
6.5.2	Width	8
6.5.3	Thickness	8
6.6	Risk assessment	8
7	Barrier properties	9
8	Biocompatibility	9
9	Clinical (human use) investigations	9
10	Microbial contamination	10
11	Bursting volume and pressure	11
11.1	Minimum values	11
11.2	Sampling and requirements	11
12	Tests for stability and shelf life	12
12.1	General	12
12.2	Procedure for determining shelf life by real-time stability studies	12
12.3	Procedure for estimating shelf life based upon accelerated stability studies	12
13	Freedom from holes	13
14	Visible defects	13
15	Packaging and labelling	13
15.1	Individual container integrity	13
15.2	Packaging	13
15.3	Labelling	14
15.3.1	Symbols	14
15.3.2	Individual containers	14

15.3.3	Consumer packages	14
15.3.4	Additional information for the consumer	15
15.3.5	Female condoms not distributed in consumer packages	16
15.4	Inspection	16
16	Data sheets	16
Annex A (normative)	Sampling plans intended for assessing conformity of a continuing series of lots of sufficient number to allow the switching rule to be applied	18
Annex B (informative)	Sampling plans intended for assessing conformity of isolated lots	19
Annex C (normative)	Determination of lubricant mass for individual female condom containers ²⁰	
Annex D (normative)	Determination of female condom length	22
Annex E (normative)	Determination of female condom width	23
Annex F (normative)	Determination of female condom thickness	24
Annex G (normative)	Testing for female condom individual container integrity	26
Annex H (normative)	Determination of barrier properties using the bacteriophage method	28
Annex I (informative)	Determination of microbial contamination	33
Annex J (normative)	Determination of bursting volume and bursting pressure	38
Annex K (normative)	Testing for holes	40
Annex L (normative)	Determination of shelf life by real-time stability studies	48
Annex M (informative)	Guidance on conducting and analysing accelerated ageing studies	50
Bibliography	53