

ISO 25841:2014-01 (E)

Female condoms - Requirements and test methods

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Quality verification	3
5	Design	4
5.1	General	4
5.2	Product insertion feature	4
5.3	Retention features	5
5.4	Lubrication	5
5.5	Dimensions	5
5.6	Risk assessment	6
6	Barrier properties	6
7	Biocompatibility	7
8	Clinical (human use) investigations	7
9	Bursting volume and pressure	8
9.1	Minimum values	8
9.2	Sampling and requirements	9
10	Tests for stability and shelf-life	9
10.1	General	9
10.2	Procedure for determining shelf-life by real-time stability studies	9
10.3	Procedure for estimating shelf-life based upon accelerated stability studies	9
11	Freedom from holes	10
12	Visible defects	10
13	Packaging and labelling	10
13.1	Package integrity	10
13.2	Packaging	10
13.3	Labelling	10
13.4	Inspection	12
14	Data sheets	13
Annex A (normative)	Sampling plans intended for assessing compliance of a continuing series of lots of sufficient number to allow the switching rule to be applied	14
Annex B (informative)	Sampling plans intended for assessing compliance of isolated lots	15

Annex C (normative) Determination of lubricant mass for individual female condom containers¹⁶	
Annex D (normative) Determination of female condom length	18
Annex E (normative) Determination of female condom width	19
Annex F (normative) Determination of female condom thickness	20
Annex G (normative) Testing for female condom package integrity	21
Annex H (normative) Determination of barrier properties using the bacteriophage method	23
Annex I (normative) Determination of bursting volume and bursting pressure	28
Annex J (normative) Testing for holes	30
Annex K (normative) Determination of shelf-life by real-time stability studies	36
Annex L (informative) Guidance on conducting and analysing accelerated ageing studies	38
Bibliography	41