ISO 4074:2015-10 (E)

Natural rubber latex male condoms - Requirements and test methods

Contents

Page

Foreword v

Introduction vii

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 Qualityverification 3

5 Lot size 3

6 Biocompatibility 4

7 Microbial contamination 4

8 Product claims 4

9 Design 4
9.1 Integral bead 4
9.2 Lubrication 4
9.3 Dimensions 5
9.3.1 Length 5
9.3.2 Width 5
9.3.3 Thickness 5

10 Bursting volume and pressure 5

11 Stability and shelf life 6
11.1 General 6
11.2 Minimum stability requirements 6
11.3 Procedure for determining shelf life by real-time stability studies 7
11.4 Estimating shelf life based upon accelerated stability studies 7

12 Freedom from holes 7

13 Visible defects 8

14 Package integrity of individual container 8

15 Packaging and labelling 8
15.1 Packaging 8
15.2 Labelling 8
15.2.1 General 8
15.2.2 Symbols 8
15.2.3 Individual container 8
15.2.4 Consumer package 9
15.2.5 Condoms not distributed in consumer packages 11
15.3 Inspection 11

16 Test report 11

Annex A (normative) Sampling plans intended for assessing compliance of a continuing seriesoflotsofsufficientnumbertoallowtheswitchingrulestobe applied 12

Annex B (informative) Sampling plans intended for assessing compliance of isolated lots 14

Annex C (normative) Determination of total lubricant for condoms in individual containers 16

Annex D (normative) Determination of length 20

Annex E (normative) Determination of width 22

Annex F (normative) Determination of thickness 23

Annex G (informative) Determination of microbial contamination 26

Annex H (normative) Determination of bursting volume and pressure 31

Annex I (normative) Oven treatment for condoms 33

Annex J (informative) Determination of force and elongation at break of test pieces of condoms.34
Annex K (normative) Determination of shelf life by real-time stability studies 37

Annex L (informative) Guidance on conducting and analysing accelerated ageing studies 40

Annex M (normative) Testing for holes 42

Annex N (normative) Testing for package integrity 48

Annex O (informative)Calibrationofairinflationequipmentfordeterminationofbursting volume and pressure 50

Annex P (informative) Recommendations for testing condoms that fall outside of the size rangesspecifiedinISO4074 54

Bibliography 56