ISO 4074:2026-03 (E)

Natural rubber latex male 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 ... 3
5 Lot size ... 4
6 Biocompatibility ... 4
7 Microbial contamination ... 4
8 Product claims ... 5
9 Design ... 5
9.1 Dimensions ... 5
9.1.1 Length ... 5
9.1.2 Nominal width ... 5
9.1.3 Thickness ... 5
9.2 Integral bead ... 5
9.3 Lubrication ... 5
10 Bursting volume and pressure ... 5
11 Stability and shelf life ... 6
11.1 General ... 6
11.2 Minimum stability requirements ... 7
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 ... 8
13 Visible defects ... 8
14 Package integrity of individual container ... 8
15 Packaging and labelling ... 9
15.1 Packaging ... 9
15.2 Labelling ... 9
15.2.1 General ... 9
15.2.2 Symbols ... 9
15.2.3 Individual container ... 9
15.2.4 Consumer package ... 9
15.2.5 Condoms not distributed in consumer packages ... 11
15.3 Inspection ... 12
16 Test report ... 12
Annex A (normative) **Sampling plans intended for assessing conformance of a continuing series of lots of sufficient number to allow the switching rules to be applied** ... 13
Annex B (informative) **Sampling plans intended for assessing conformance of isolated lots** ... 15
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** **38**
Annex J (informative) **Determination of force and elongation at break of test pieces of condoms** **39**
Annex K (normative) **Determination of shelf life by real-time stability studies** **42**
Annex L (informative) **Guidance on conducting and analysing accelerated ageing studies** **45**
Annex M (informative) **Testing for holes** **50**
Annex N (normative) **Testing for package integrity** **62**
Annex O (normative) **Calibration of air inflation equipment for determination of bursting volume and pressure** **66**
Annex P (normative) **Requirements for testing condoms that fall outside of the length and width ranges specified in Clause 9** **72**
Annex Q (normative) **Verification procedure for the freedom from holes test** **74**
Bibliography **79**