

ISO 16038:2017-11 (E)

Male condoms - Guidance on the use of ISO 4074 and ISO 23409 in the quality management of condoms

Contents	Page
Foreword	iv
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Quality of design	1
4.1 General	1
4.2 Clinical investigation	3
4.3 Risk management	3
4.3.1 Risk analysis and risk management	3
4.3.2 Latex allergy	3
4.3.3 Microbial contamination (bioburden)	4
4.3.4 Nitrosamines	4
5 Quality of manufacture	4
5.1 Quality management	4
5.2 Lot testing (finished product testing)	4
5.3 Rounding-off values	5
6 Quality in procurement	5
7 Quality in testing	6
8 Important parameters to consider when using ISO 4074 and ISO 23409	6
8.1 Application of ISO 4074 and ISO 23409	6
8.2 Dimensions	6
8.3 Visibly open seals	7
8.4 Justification of additional claims	7
8.5 Compatibility of materials	7
8.6 Freedom from holes	8
8.7 Shelf life and resistance to degradation	8
8.8 Packaging and labelling	9
8.9 Type testing	10
8.10 Lubricants	10
9 Sampling	10
Bibliography	11