

# ISO 16038:2017-11 (E)

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

---

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		vi
<b>1</b>	<b>Scope .....</b>	<b>1</b>
<b>2</b>	<b>Normative references .....</b>	<b>1</b>
<b>3</b>	<b>Terms and definitions .....</b>	<b>1</b>
<b>4</b>	<b>Quality of design .....</b>	<b>1</b>
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
<b>5</b>	<b>Quality of manufacture .....</b>	<b>4</b>
5.1	Quality management .....	4
5.2	Lot testing (finished product testing) .....	4
5.3	Rounding-off values .....	5
<b>6</b>	<b>Quality in procurement .....</b>	<b>5</b>
<b>7</b>	<b>Quality in testing .....</b>	<b>6</b>
<b>8</b>	<b>Important parameters to consider when using ISO 4074 and ISO 23409 .....</b>	<b>6</b>
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
<b>9</b>	<b>Sampling .....</b>	<b>10</b>
Bibliography .....		11