

# 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          |
| 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          |