

ISO/TR 24484:2023-01 (E)

Female condoms - Use of ISO 25841 and the quality management of female condoms

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Quality of design	2
4.1	General	2
4.2	Design input and design development	2
4.2.1	General	2
4.2.2	Barrier sheath	3
4.2.3	Product insertion feature and retention feature	3
4.2.4	Dressing materials	4
4.2.5	Lubricants	4
4.2.6	Biocompatibility	4
4.2.7	Control of bioburden	4
4.2.8	Packaging	4
4.3	Design verification	5
4.4	Design validation	5
4.4.1	Evaluation of barrier properties	5
4.4.2	Clinical (human use) investigations	5
4.4.3	Stability studies and shelf-life claim	5
4.5	Design output	6
4.5.1	General	6
4.5.2	Details of materials	6
4.5.3	Specifications of the female condoms	6
4.5.4	Supporting information	7
4.5.5	Regulatory compliance	7
4.6	Design transfer	7
4.7	Validation and change controls	7
5	Risk management	7
6	Quality in manufacture	8
7	Quality in testing	10
7.1	General	10
7.2	Test equipment	11
7.3	Sampling and testing:	11
7.4	Training and competence of personnel in testing	11
7.5	Review of results and reports:	11
8	Quality in procurement	12
9	Handling and disposal of used female condoms	12
Bibliography		13