

ISO 3533:2021-09 (E)

Sex toys - Design and safety requirements for products in direct contact with genitalia, the anus, or both

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	General requirements for risk management	2
4.1	General	2
4.2	Risk analysis process	2
4.3	Risk assessment	3
4.4	Post-market control	3
5	Design requirements	3
5.1	General	3
5.1.1	Anal use products	3
5.2	Mechanical hazards	3
5.2.1	Prevention of retention	3
5.2.2	Products for genital enclosure	4
5.2.3	Moving and removable parts	4
5.3	Vibration	4
5.4	Electrical safety	4
5.4.1	Electrical stimulation	5
5.5	Surface temperature	5
5.6	Design requirement for wireless remote-controlled products	5
5.7	Surfaces, corners, edges, and protruding parts	5
6	Materials	5
6.1	General	5
6.2	Material safety	5
6.3	Biocompatibility	6
6.4	Cleaning and maintenance	6
7	User information	6
7.1	General	6
7.2	Content of user information on product	6
7.3	Packaging	6
7.4	Additional user information	7
Annex A (informative) Guidance on risk management		8
Annex B (informative) Design considerations based on anatomy		11
Annex C (informative) Guidance for creating a Restricted Substance List		14
Bibliography		15