

ISO 20342-1:2019 (E)

Assistive products for tissue integrity when lying down — Part 1: General requirements

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	General requirements and safety
4.1	General requirements
4.2	Intended use
4.2.1	General requirements
4.2.2	Consideration regarding intended use
4.2.3	Intended use statement
4.2.3.1	Claims
4.2.3.2	APTI description
4.2.3.3	Users and application environments
4.3	APTI risk management
4.4	APTI usability
4.4.1	General
4.4.2	Design requirements in relation to persons with cognitive impairment
4.5	Design controls
4.6	Clinical evaluation
4.7	Foreseeable misuse
4.8	Test conditions
4.9	Lifting and carrying means
5	Safety requirements
5.1	Requirements for information supplied by the manufacturer
5.1.1	General
5.1.2	APTI traceability
5.1.3	Education and training
5.1.4	Pre-sale information
5.1.5	User information
5.1.6	Service information and inspection
5.1.7	Labelling
5.1.8	Marking of user weight and maximum load
5.1.9	Packaging
5.2	APTI which can be dismantled
5.2.1	General requirements
5.2.2	Small parts
5.2.3	Fasteners and connections
5.3	Resistance to corrosion
5.4	Noise and vibration
5.5	Sound audible acoustic energy
5.6	Default indicators
5.7	Feedback
6	Flammability
6.1	General
6.2	Flammability

- 6.3 Moulded parts used as enclosures for electrical equipment
- 7 Mechanical safety
 - 7.1 Prevention of traps for the human body
 - 7.2 Safety of moving and folding parts
 - 7.3 V-shaped openings
 - 7.4 Surfaces, corners, edges and protruding parts
 - 7.5 Folding and adjusting mechanisms
 - 7.6 Instability hazard
 - 7.7 Temperature of parts that come into contact with human skin
 - 7.8 Ergonomic principles
 - 7.9 Additional consideration
- 8 Safety of electrical equipment
 - 8.1 General electrical requirements
 - 8.2 Electromagnetic compatibility
 - 8.2.1 General
 - 8.2.2 Emissions
 - 8.2.3 Immunity
 - 8.2.4 Power frequency magnetic field immunity
 - 8.3 Liquid ingress
 - 8.4 Interruption of power supply/supply mains to an APTI
 - 8.5 Hold to run activation
 - 8.6 Emergency stop functions
- 9 Biocompatibility
 - 9.1 Biocompatibility and toxicity
 - 9.2 Animal tissue
- 10 Contamination
 - 10.1 Liquid ingress
 - 10.2 Cleaning and disinfection
 - 10.3 Cross infection and microbial contamination
- Annex A (informative) General information
 - A.1 General requirements (4.1)
 - A.2 Design controls (4.5)
 - A.3 Packaging (5.1.9)
 - A.4 Noise and vibration (5.4)
 - A.5 Flammability (6)
 - A.6 Ergonomic principles (7.8)
 - A.7 Immunity (8.2.3)
 - A.8 Cleaning and disinfection (10.2)
 - A.9 Moisture vapour permeability/microclimate management
- Annex B (informative) Environmental and consumer related guidance
 - B.1 Assessment of hazardous substances in an APTI — General aspects
 - B.2 Hazardous substances in all materials of an APTI
 - B.2.1 Substances of very high concern (SVHC): the European approach on chemicals
 - B.2.1.1 General
 - B.2.1.2 CMR Chemicals
 - B.2.1.3 PBT and vPvB substances
 - B.2.1.4 Substances of equivalent concern
 - B.2.2 Recommendations
 - B.2.2.1 CMR Chemicals
 - B.2.2.2 PBT and vPvB substances
 - B.2.2.3 Substances of equivalent concern
 - B.3 Hazardous substances in textiles
 - B.3.1 Relevant substances
 - B.4 Hazardous substances in plastic materials
 - B.4.1 Relevant substances
 - B.4.2 Recommendation
 - B.4.2.1 Substances based on lead, cadmium, mercury and their compounds or organo tin compounds

- B.4.2.2 Organic halogenated compounds**
- B.4.2.3 Phthalates**
- B.5 Metals**
- B.5.1 Relevant substances**
- B.6 Wooden parts**
- B.6.1 Relevant substances**
- B.6.2 Recommendations**

Annex C (informative) Periodic inspection

Page count: 36