

# DIN EN ISO 21856:2022-12 (E)

## Assistive products - General requirements and test methods (ISO 21856:2022)

---

<b>Contents</b>		<b>Page</b>
<b>European foreword</b>		<b>5</b>
<b>Foreword</b>		<b>6</b>
<b>Introduction</b>		<b>7</b>
<b>1 Scope</b>		<b>8</b>
<b>2 Normative references</b>		<b>8</b>
<b>3 Terms and definitions</b>		<b>10</b>
<b>4 General requirements</b>		<b>14</b>
4.1 Risk analysis and management		14
4.2 Intended performance and technical documentation		15
4.3 Clinical evaluation and investigation		15
4.4 Assistive products that can be dismantled		15
4.5 Fasteners		15
4.6 Load limits		15
4.7 Immobilising means		16
4.8 Usability		16
4.9 Design requirements in relation to persons with sensory and cognitive impairments		16
4.10 Considerations for accessibility		16
4.11 Feedback		16
<b>5 Materials</b>		<b>16</b>
5.1 General		16
5.2 Flammability		16
5.2.1 General		16
5.2.2 Upholstered parts, mattresses, bed bases, bedding and textiles		17
5.2.3 Polymeric parts		18
5.2.4 Electrical components		18
5.2.5 Wiring		18
5.3 Biocompatibility and toxicity		18
5.4 Contaminants and residues		19
5.4.1 General		19
5.4.2 Substances that can leak from an assistive product in intended use and in fault conditions		19
5.5 Infection and microbiological contamination		19
5.5.1 Introduction		19
5.5.2 Cleaning and disinfection		19
5.5.3 Machine washable assistive products		20
5.5.4 Animal tissue		21
5.6 Resistance to corrosion		21
<b>6 Emitted sound and vibration</b>		<b>21</b>
6.1 Noise and vibration		21
6.2 Sound levels and frequencies of audible warning devices		21
<b>7 Electromagnetic compatibility</b>		<b>22</b>
<b>8 Electrical safety</b>		<b>22</b>
8.1 General		22

8.2	Battery powered assistive products - Charge level indicator .....	22
8.3	Electrically heated blankets, pads and similar flexible heating appliances .....	22
8.4	Ingress of liquids or particulate matter .....	22
8.4.1	Ingress of liquids .....	22
8.4.2	Ingress of particulate matter .....	23
8.5	Pendant controls .....	23
<b>9</b>	<b>Overflow, spillage, leakage and ingress of liquids .....</b>	<b>23</b>
9.1	Overflow .....	23
9.1.1	Requirements .....	23
9.1.2	Test method .....	23
9.2	Spillage .....	24
9.2.1	Requirements .....	24
9.2.2	Test method .....	24
9.3	Leakage .....	24
9.4	Ingress of liquids .....	24
9.4.1	Requirements .....	24
9.4.2	Test method .....	24
<b>10</b>	<b>Surface temperature .....</b>	<b>24</b>
<b>11</b>	<b>Sterility .....</b>	<b>25</b>
11.1	Sterility requirements .....	25
11.2	Sterilization processes .....	25
11.3	Maintenance of sterility in transit .....	26
<b>12</b>	<b>Safety of moving parts .....</b>	<b>26</b>
12.1	Squeezing .....	26
12.2	Mechanical wear .....	27
12.3	Emergency stopping functions .....	27
<b>13</b>	<b>Means to prevent falling out .....</b>	<b>27</b>
13.1	General .....	27
13.2	Protection against inadvertent user falls in relation to side rails .....	27
<b>14</b>	<b>Prevention of traps for parts of the human body .....</b>	<b>29</b>
14.1	Holes and clearances .....	29
14.2	V-shaped openings .....	30
<b>15</b>	<b>Folding and locking mechanisms .....</b>	<b>30</b>
15.1	General .....	30
15.2	Locking mechanisms .....	30
15.3	Prevention of trap and squeeze hazards .....	31
<b>16</b>	<b>Carrying handles .....</b>	<b>31</b>
16.1	General .....	31
16.2	Requirement .....	31
16.3	Test method .....	31
<b>17</b>	<b>Assistive products that support or suspend users .....</b>	<b>32</b>
17.1	General .....	32
17.2	Static forces .....	32
17.2.1	Assistive products that support users .....	32
17.2.2	Assistive products that suspend users .....	33
17.3	Dynamic forces .....	33
17.4	Requirements and test method for tips .....	33
17.4.1	General .....	33
17.4.2	Friction of tips .....	33
17.4.3	Durability of tips .....	33

<b>18</b>	<b>Portable and mobile assistive products</b> .....	<b>34</b>
18.1	Portable assistive products.....	34
18.2	Mobile assistive products.....	34
<b>19</b>	<b>Surfaces, corners, edges and protruding parts</b> .....	<b>35</b>
<b>20</b>	<b>Hand-held assistive products</b> .....	<b>35</b>
<b>21</b>	<b>Assistive products for children</b> .....	<b>36</b>
<b>22</b>	<b>Stability</b> .....	<b>36</b>
<b>23</b>	<b>Forces in soft tissues of the human body</b> .....	<b>37</b>
<b>24</b>	<b>Ergonomic principles</b> .....	<b>37</b>
<b>25</b>	<b>Requirements for information supplied by the manufacturer</b> .....	<b>37</b>
25.1	General.....	37
25.2	Instructions for use.....	38
25.2.1	General.....	38
25.2.2	Pre-sale information.....	38
25.2.3	User information.....	39
25.2.4	Service information.....	39
25.3	Labelling.....	40
<b>26</b>	<b>Packaging</b> .....	<b>41</b>
<b>27</b>	<b>Test report</b> .....	<b>41</b>
<b>28</b>	<b>Guidelines for accessible information on assistive products</b> .....	<b>42</b>
<b>Annex A (informative) General recommendations</b> .....		<b>43</b>
<b>Annex B (informative) Environmental and consumer related guidance</b> .....		<b>51</b>
<b>Annex C (informative) Guidelines for accessible information on assistive products</b> .....		<b>56</b>
<b>Bibliography</b> .....		<b>60</b>