| | Assistive products and List of standards develope | • | | | |
|--------------------------|---|--|--------------------------------|--------------------|-------------------|
| Standards | Title | Corresponding Indian Standards no, if any | Indian Suitability (Yes/No) | Priority (1,2.3,4) | Status of adoptio |
| EN ISO 11334-1:2007 | Assistive products for walking manipulated by one arm - Requirements and test methods - Part 1: Elbow crutches (ISO 11334- | | | | |
| EN ISO 8670-2:1996 | 1:2007) Ostomy collection bags - Part 2: Requirements and test methods (ISO 8670-2:1996) | | | | |
| EN ISO 8669-2:1996 | Urine collection bags - Part 2: Requirements and test methods (ISO 8669-2:1996) | | | | |
| EN ISO 22675:2016 | Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods (ISO 22675:2016) | | | | |
| EN ISO 21856:2022 | Assistive products - General requirements and test methods (ISO 21856:2022) | | | | |
| EN 12183:2022 | Manual wheelchairs - Requirements and test methods | | | | |
| EN ISO 21801-2:2022 | Cognitive accessibility - Part 2: Reporting (ISO 21801-2:2022) | | | | |
| EN ISO 21801-1:2021 | Cognitive accessibility - Part 1: General guidelines (ISO 21801- 1:2020) | | | | |
| EN ISO 21802:2021 | Assistive products - Guidelines on cognitive accessibility - Daily time management (ISO 21802:2019) | | | | |
| CEN ISO/TS 20342-10:2022 | Assistive products for tissue integrity when lying down - Part 10: Guidance to cleaning, disinfecting and care of polyurethane APTI covers (ISO/TS 20342-10:2022) | | | | |
| EN ISO 22523:2006 | External limb prostheses and external orthoses - Requirements and test methods (ISO 22523:2006) | | | | |
| EN ISO 24415-1:2009 | Tips for assistive products for walking - Requirements and test methods - Part 1: Friction of tips (ISO 24415-1:2009) | | | | |
| EN ISO 11334-4:1999 | Walking aids manipulated by one arm - Requirements and test methods - Part 4: Walking sticks with three or more legs (ISO 11334- 4:1999) | | | | |
| EN ISO 22748:2021 | Absorbent incontinence products for urine and/or faeces - Product type names and illustrations (ISO 22748:2021) | | | | |
| EN ISO 10535:2021 | Assistive products - Hoists for the transfer of persons - Requirements and test methods (ISO 10535:2021, Corrected version 2023-08) | | | | |
| EN ISO 11199-2:2021 | Assistive products for walking manipulated by both arms - Requirements and test methods - Part 2: Rollators (ISO 11199- 2:2021) | | | | |
| EN ISO 10328:2016 | Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods (ISO 10328:2016) | | | | |
| EN ISO 9999:2022 | Assistive products - Classification and terminology (ISO 9999:2022) | | | | |
| EN 12184:2022 | Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods | | | | |
| CEN ISO/TR 20342-7:2022 | Assistive products for tissue integrity when lying down - Part 7: Foam properties, characteristics and performance (ISO/TR 20342- 7:2021) | | | | |
| EN 1985:1998 | Walking aids - General requirements and test methods | | | | |
| EN ISO 11199-3:2005 | Walking aids manipulated by both arms - Requirements and test methods - Part 3: Walking tables (ISO 11199-3:2005) | | | | |
| EN ISO 20342-1:2022 | Assistive products for tissue integrity when lying down - Part 1: General requirements (ISO 20342-1:2022) | | | | |
| EN ISO 15621:2017 | Absorbent incontinence aids for urine and/or faeces - General guidelines on evaluation (ISO 15621:2017) | | | | |
| EN ISO 16021:2024 | Absorbent incontinence products for urine and/or faeces - Basic principles for evaluation of single-use adult products from the perspective of users and caregivers (ISO 16021:2024) | | | | |
| EN ISO 11199-1:2021 | Assistive products for walking manipulated by both arms - Requirements and test methods - Part 1: Walking frames (ISO 11199- 1:2021) | | | | |
| | CEN/CLC/JTC 16 - Active Implant | table Medical Devices | | | |
| EN 45502-2-2:2008 | Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators) | | | | |

| EN 45502-1:2015 | Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer | | | |
|--|---|------------------------|---|--|
| EN ISO 14708-3:2022 | Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators (ISO 14708-3:2017) | | | |
| EN ISO 14708-4:2022 | Implants for surgery - Active implantable medical devices - Part 4: Implantable infusion pump systems (ISO 14708-4:2022) | | | |
| EN ISO 14708-5:2022 | Implants for surgery - Active implantable medical devices - Part 5: Circulatory support devices (ISO 14708-5:2020) | | | |
| EN ISO 14708-2:2022 | Implants for surgery - Active implantable medical devices - Part 2: Cardiac pacemakers (ISO 14708-2:2019) | | | |
| EN ISO 14708-7:2022 | Implants for surgery - Active implantable medical devices - Part 7: Particular requirements for cochlear and auditory brainstem implant systems (ISO 14708-7:2019) | | | |
| EN ISO 14708-6:2022 | Implants for surgery - Active implantable medical devices - Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) (ISO 14708-6:2019) | | | |
| EN 45502-2-1:2003 | Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers) | | | |
| EN 45502-2-2:2008/corrigendum Apr. 2009 | Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators) | | | |
| EN 45502-2-3:2010 | Active implantable medical devices - Part 2-3: Particular requirements for cochlear and auditory brainstem implant systems | | | |
| | List of standards developed by | / ETSI TC on eHealth | 1 | |
| ETSI TR 103 477 V1.3.1 (2023-01) | eHEALTH; Standardization use cases for eHealth | | | |
| ETSI SR 003 809 V1.1.2 (2021-12) | eHEALTH; The role of ICT to enable Health crisis management and recovery; Responding to the 2019 SARS-CoV-2 Pandemic | | | |
| ETSI SR 003 809 V1.1.1 (2021-09) | eHEALTH; The role of ICT to enable Health crisis management and recovery; Responding to the 2019 SARS-CoV-2 Pandemic | | | |
| ETSI TR 103 477 V1.2.1 (2020-08) ETSI TR 103 477 V1.1.1 (2019-10) | eHEALTH; Standardization use cases for eHealth eHEALTH; Standardization use cases for eHealth | | | |
| ETSI TR 102 764 V1.1.1 (2009-02) | eHEALTH; Architecture; Analysis of user service models, technologies and applications supporting eHealth | | | |
| ETSI SR 002 564 V2.0.0 (2007-05) | Applicability of existing ETSI and ETSI/3GPP deliverables to eHealth | | | |
| | Standards developed by ISO/TC | 173 Assistive products | | |
| <u>ISO 10535:2021</u> | Assistive products — Hoists for the transfer of persons — Requirements and test methods | | | |
| <u>ISO 11199-1:2021</u> | Assistive products for walking manipulated by both arms — Requirements and test methods — Part 1: Walking frames | | | |
| <u>ISO 11199-2:2021</u> | Assistive products for walking manipulated by both arms — Requirements and test methods — Part 2: Rollators | | | |
| <u>ISO 11199-3:2005</u> | Walking aids manipulated by both arms — Requirements and test methods — Part 3: Walking tables | | | |
| <u>ISO 11334-1:2007</u> | Assistive products for walking manipulated by one arm — Requirements and test methods — Part 1: Elbow crutches | | | |
| <u>ISO 11334-4:1999</u> | Walking aids manipulated by one arm — Requirements and test methods — Part 4: Walking sticks with three or more legs | | | |
| <u>ISO/TR 11548-1:2001</u> | Communication aids for blind persons — Identifiers, names and assignation to coded character sets for 8-dot Braille characters — Part 1: General guidelines for Braille identifiers and shift marks | | | |
| <u>ISO/TR 11548-2:2001</u> | Communication aids for blind persons — Identifiers, names and assignation to coded character sets for 8-dot Braille characters — Part 2: Latin alphabet based character sets | | | |
| <u>ISO 17966:2016</u> | Assistive products for personal hygiene that support users — Requirements and test methods | | | |
| ISO 19894:2019 | Walking trolleys — Requirements and test methods | | | |
| | Assistive products for tissue integrity when lying down — Part 1: General requirements | | | |
| ISO/TR 20342-7:2021 | Assistive products for tissue integrity when lying down — Part 7: | | 1 | |

| 150/75 20242 40/2022 | Assistive products for tissue integrity when lying down — Part 10: | | | | |
|---------------------------------------|---|-----------------------------|------------------|---|---|
| <u>ISO/TS 20342-10:2022</u> | Guidance to cleaning, disinfecting and care of polyurethane APTI covers | | | | |
| ISO 21801-1:2020 | Cognitive accessibility — Part 1: General guidelines | | | | |
| <u>ISO 21801-2:2022</u> | Cognitive accessibility — Part 2: Reporting | | | | |
| <u>ISO 21802:2019</u> | Assistive products — Guidelines on cognitive accessibility — Daily time management | | | | |
| <u>ISO 21856:2022</u> | Assistive products — General requirements and test methods | | | | |
| <u>ISO 23599:2019</u> | Assistive products for blind and vision-impaired persons — Tactile walking surface indicators | | | | |
| <u>ISO 23600:2007</u> | Assistive products for persons with vision impairments and persons with vision and hearing impairments — Acoustic and tactile signals for pedestrian traffic lights | | | | |
| <u>ISO 24415-1:2009</u> | Tips for assistive products for walking — Requirements and test methods — Part 1: Friction of tips | | | | |
| <u>ISO 24415-2:2011</u> | Tips for assistive products for walking — Requirements and test methods — Part 2: Durability of tips for crutches | | | | |
| IEC 60601-2-52:2009 | Medical electrical equipment — Part 2-52: Particular requirements for the basic safety and essential performance of medical beds | | | | |
| IEC 60601-2-52:2009/Amd 1:2015 | Medical electrical equipment — Part 2-52: Particular requirements for the basic safety and essential performance of medical beds — Amendment 1 | | | | |
| <u>IEC 60601-2-52:2009/Cor 1:2010</u> | Medical electrical equipment — Part 2-52: Particular requirements for the basic safety and essential performance of medical beds — Technical Corrigendum 1 | | | | |
| | List of standards developed by IEC Sy | CAAL (active assisted livir | ng) | | L |
| | Cooperative multiple systems in connected home environments - | | | | |
| IEC 63168 ED1 | AAL functional safety requirements of electronic safety-related systems | | | | |
| <u>IEC 63240-1 ED2</u> | Active assisted living (AAL) reference architecture and architecture model - Part 1: Reference architecture | | | | |
| IEC 63310 ED1 | Functional performance criteria for AAL robots used in connected home environment | | | | |
| | Active Assisted Living (AAL) guidance for education and training of | | | | |
| IEC SRD 63314 ED1 | persons working in the field of AAL Safety Aspects – Guideline for Adult AAL Care Recipients in | | | | |
| IEC SRD 63408 ED1 | standards and other specifications Cooperative Multiple Systems in Connected Home Environments – | | | | |
| <u>IEC SRD 63420 ED1</u> | AAL SOTIF of E/E Systems Functional performance criteria for AAL robots used in connected | | | | |
| IEC SRD 63426 ED1 | home environment Ageing societies – A Guide to enhancing safety and convenience for | | | | |
| <u>ISO TS 25558 ED1</u> | older persons in smart home environment | | | | |
| - | ISO technical committee ISO, | TC 159, Ergonomics | | 1 | |
| ISO/TR 22411:2021 | Ergonomics data for use in the application of ISO/IEC Guide 71:2014 | | | | |
| | ISO technical committee ISO/TC 59/SC 16, Accessib | lity and usability of the b | uilt environment | | |
| ISO 21542:2021 | Building construction — Accessibility and usability of the built | | | | |
| | environment ISO/IEC JTC | 1 | | 1 | 1 |
| | Information technology — W3C Web Content Accessibility | | | | |
| ISO/IEC 40500:2012 | Guidelines (WCAG) 2.0 | | | | |
| | IEC TC 124- Wearable electronic d | evices and technologies | | | |
| | Wearable electropic devices and the basis of the Dark 400 fr | | | | |
| | Wearable electronic devices and technologies - Part 402-1: Performance measurement of fitness wearables - Test methods of | | | | |
| IEC 63203-402-1:2022 | glove-type motion sensors for measuring finger movements | | | | |
| | Wearable electronic devices and technologies - Part 402-3: | | | | |
| | Performance measurement of fitness wearables - Test methods for | | | | |
| IEC 63203-402-3:2024 | the determination of the accuracy of heart rate ISO/TC 215 - Health | nformatics | | | |
| | | | | | |
| | Health informatics — Interoperability of public health emergency preparedness and response information systems | | | | |
| ISO 5477:2023 | | | | | |
| ISO/IEEE 11073-00103:2015 | Health informatics — Personal health device communication — Part 00103: Overview | | | | |
| ISO/IEEE 11073-10101:2020 | Health informatics — Device interoperability — Part 10101: Point-of- care medical device communication — Nomenclature | | | | |
| | | | | | |

| ISO/IEEE 11073-10102:2014 | Health informatics — Point-of-care medical device communication — Part 10102: Nomenclature — Annotated ECG |
|---|---|
| ISO/IEEE 11073-10103:2014 | Health informatics — Point-of-care medical device communication — Part 10103: Nomenclature — Implantable device, cardiac |
| ISO/IEEE 11073-10201:2020 | Health informatics — Device interoperability — Part 10201: Point-of- care medical device communication — Domain information model |
| ISO/IEEE 11073-10207:2019 | Health informatics — Personal health device communication — Part 10207: Domain information and service model for service-oriented point-of-care medical device communication |
| ISO/IEEE 11073-10404:2022 | Health informatics — Device interoperability — Part 10404: Personal health device communication — Device specialization — Pulse oximeter |
| ISO/IEEE 11073-10407:2022 | Health informatics — Device interoperability — Part 10407: Personal health device communication — Device specialization — Blood pressure monitor |
| ISO/IEEE 11073-10408:2022 | Health informatics — Device interoperability — Part 10408: Personal health device communication — Device specialization — Thermometer |
| ISO/IEEE 11073-10415:2022 | Health informatics — Device interoperability — Part 10415: Personal health device communication — Device specialization — Weighing scale Health informatics — Device interoperability — Part 10420: Personal |
| ISO/IEEE 11073-10420:2022 | health device communication — Device specialization — Body composition analyzer |
| ISO/IEEE 11073-20101:2004 | Health informatics — Point-of-care medical device communication — Part 20101: Application profiles — Base standard |
| ISO/IEEE 11073-20601:2022 | Health informatics — Device interoperability — Part 20601: Personal health device communication — Application profile — Optimized exchange protocol |
| ISO/IEEE 11073-20701:2020 | Health informatics — Device interoperability — Part 20701: Point-of- care medical device communication — Service oriented medical device exchange architecture and protocol binding |
| ISO/IEEE 11073-20702:2018 | Health informatics — Point-of-care medical device communication — Part 20702: Medical devices communication profile for web services |
| ISO/IEEE 11073-30200:2004 | Health informatics — Point-of-care medical device communication — Part 30200: Transport profile — Cable connected |
| ISO/IEEE 11073-30200:2004/Amd 1:2015 | Health informatics — Point-of-care medical device communication — Part 30200: Transport profile — Cable connected — Amendment 1 |
| ISO/IEEE 11073-30400:2012 | Health informatics — Point-of-care medical device communication — Part 30400: Interface profile — Cabled Ethernet |
| ISO/IEEE 11073-40101:2022 | Health informatics — Device interoperability — Part 40101: Foundational — Cybersecurity — Processes for vulnerability assessment |
| SO/IEEE 11073-40102:2022 | Health informatics — Device interoperability — Part 40102: Foundational — Cybersecurity — Capabilities for mitigation |
| ISO 11073-90101:2008 | Health informatics — Point-of-care medical device communication — Part 90101: Analytical instruments — Point-of-care test |
| ISO 12052:2017 | Health informatics — Digital imaging and communication in medicine (DICOM) including workflow and data management |
| ISO 13131:2021 | Health informatics — Telehealth services — Quality planning guidelines |
| SO/TR 16056-1:2004 | Health informatics — Interoperability of telehealth systems and networks — Part 1: Introduction and definitions |
| ISO/TR 16056-2:2004 | Health informatics — Interoperability of telehealth systems and networks — Part 2: Real-time systems Health informatics — Interoperability and integration reference |
| ISO 23903:2021 | architecture — Model and framework |