

**Government of India**  
**Ministry of Consumer Affairs, Food and Public Distribution**  
**Department of Consumer Affairs**

**LOK SABHA**  
**UNSTARRED QUESTION NO. 3754**  
**TO BE ANSWERED ON 18.12.2024**

**DEVELOPMENT OF STANDARDS FOR MEDICAL ASSISTIVE TECHNOLOGIES**

3754. SHRI RAJU BISTA:

Will the Minister of **CONSUMER AFFAIRS, FOOD AND PUBLIC DISTRIBUTION**  
**उपभोक्ता मामले, खाद्य और सार्वजनिक वितरण राज्य मंत्री** be pleased to state:

- (a) the specific types of medical assistive technologies for which the Bureau of Indian Standards (BIS) is currently developing standards;
- (b) the timeline set by BIS for the completion of these standards particularly for the 214 critical medical devices identified in consultation with the Department of Pharmaceuticals (DoP);
- (c) the measures being taken by BIS to ensure that these standards align with international benchmarks thereby enhancing the global competitiveness of Indian medical devices;
- (d) the strategies employed by BIS to engage with stakeholders including manufacturers, healthcare professionals and patient advocacy groups in the development of these standards to ensure that they meet the needs of end-users; and
- (e) whether there are any additional initiatives or collaborations planned by BIS to further improve the quality, safety and affordability of medical assistive technologies in India beyond the development of these standards and if so, the details thereof?

**ANSWER**

**उपभोक्ता मामले, खाद्य और सार्वजनिक वितरण राज्य मंत्री**  
**(श्री बी.एल. वर्मा )**

**THE MINISTER OF STATE**  
**CONSUMER AFFAIRS, FOOD AND PUBLIC DISTRIBUTION**  
**(SHRI B.L.VERMA)**

(a) : Artificial Limbs, Rehabilitation Appliances and Equipment for the Persons with Disability' Sectional Committee on Medical and Hospital Planning Department (MHD) 9 of Bureau of Indian Standards (BIS) is engaged in formulation of Indian Standards on assistive technologies. The scope of Committee includes formulation of Indian Standards for artificial limbs, prosthetic and orthotic appliances, and rehabilitation equipment. The list of standards developed with respect to assistive technologies by MHD 9 Sectional Committee is given at **Annexure-I**.

Further, the Indian Standards on following types of assistive technologies are currently under development by MHD 9 Sectional Committee:

- (i) Standards on Accessible Design:
  - a) Accessible Design Application of Braille on Signage Equipment and Appliances,
  - b) Accessible design information contents figuration and display methods of tactile guide maps
- (ii) Standards identified by ICMR under the National List of Essential Assistive Products (NLEAP):
  - a) Electronic Travel Aids,
  - b) Portable Ramps
- (iii) Assistive products for walking (Crutches and Walking sticks)

(b) : The list of 214 medical devices identified in consultation with Departmental of Pharmaceuticals (DoP) is exclusive of the subjects relating to assistive products. The 214 devices identified in consultation with DoP have been segregated into Priority List-I and II. Development of Indian Standards on devices in Priority List-I is planned to be completed by March 2025. Development of Indian Standards on devices listed in Priority List-II is planned to be completed by December 2025. Priority List-I and Priority List-II are given at **Annexure-II** and **Annexure-III** respectively.

(c) : BIS recognizes that harmonization of national standards with international standards is necessary to provide opportunities for Indian industries to be globally competitive and have market access. Therefore, Indian Standards are always developed to meet the particular needs in India, while aligning with global best practices and benchmarks. Rule 29 of *BIS Rules*, 2018 provides for adoption of International Standards developed by ISO/IEC as Indian Standards. Wherever, International Standard developed by ISO/IEC exists for any specific medical device including for assistive products, the concerned technical committee of BIS invariably reviews the same viz-a-viz the national interest and requirements. The International Standard is adopted as an Indian Standard wherever found suitable. Currently, out of 1102 number of product standards on medical devices, 404 numbers of Indian Standards are identical or technically equivalent adoption of ISO/IEC Standards.

To facilitate the adoption of international standards, it is necessary that national requirements get addressed at the time of development of international standards. Participating in Technical Committees and Subcommittees of international standards bodies (ISO/IEC) enables India to comment on draft standards and pursue the incorporation of requirements that are of interest of Indian stakeholders. BIS represents India at the ISO/IEC Technical Committees that involve standardization of medical devices at the international level i.e. *ISO/TC 173 'Assistive Products'*.

(d) : Development of Indian Standards including standards for medical devices is a collective output of the technical committees which are representative of a balance of stakeholder ranging from consumers, government/regulatory bodies, industry, industry/manufacturer associations, technologists, R&D organizations, scientific institutes, academic and technical institutions, professional bodies/institutes, testing/ calibration laboratories, accreditation bodies and individual experts.

Further, all draft Indian Standards are issued into wide circulation for a period of not less than one month and hosted on BIS website for free access to the public for comments. The comments received from all concerned stakeholders are considered and resolved by the concerned technical committee before the draft Indian Standard is finalized and adopted as an Indian Standards.

The process provides for consideration and validation of technical viewpoints and evaluation of comments and feedback from public consultations before the Indian Standard is finalized and published. This ensures that the provisions of the Indian Standard are acceptable to all stakeholders and meet the need of the end-users.

(e) : BIS also carries out Standard promotion activities through engagement of stakeholders and awareness programmes for consumers. Conformity assessment activity by BIS through certification schemes also ensures the quality and safety of medical assistive technologies.

**ANNEXURE REFERRED TO IN REPLY TO PART (a) OF LOK SABHA UNSTARRED QUESTION NUMBER NO.3754 FOR ANSWER ON 18.12.2024 REGARDING DEVELOPMENT OF STANDARDS FOR MEDICAL ASSISTIVE TECHNOLOGIES.**

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Details of Published Standards are as under:-

S.No.	IS No.	Title
1	IS 10110 : 1982	Specification for table spoon terminal device for artificial limbs
2	IS 10111 : 1982	Specification for table fork terminal device for artificial limbs
3	IS 10537 : 1983	Specification for ankle bolt for such foot
4	IS 10538 : 1983	Specification for kitchen knife terminal device for artificial limbs
5	IS 10539 : 1983	Specification for sickle terminal device for artificial limbs
6	IS 10926 : 1984	Specification for tweezer terminal device for artificial limbs
7	IS 10928 : 1984	Specification for table, tilting, manual
8	IS 10929 : 1984	Specification for hook voluntary opening terminal device for artificial limbs
9	IS 10976 : 1993/ISO 6440	Wheelchairs - Nomenclature, terms and definitions (First Revision)
10	IS 11242 : 1985	Specification for lumbo - Sacral flexion - Extension and lateral - Flexion control brace
11	IS 11243 : 1985	Specification for thoraco - Lumbo - Sacral flexion - Extension and lateral - Flexion control brace
12	IS 11279 : 1985	Specification for braille slate
13	IS 11279 : 2024	Braille Slate — Specification
14	IS 11316 : 1985	Specification for cosmetic hand, artificial limb
15	IS 11646 (Part 1) : 2003	Cane for visually handicapped - Specification: Part 1 rigid, long and white (First Revision)
16	IS 11646 (Part 2) : 1986	Specification for cane for visually handicapped: Part 2 folding type
17	IS 11647 : 1986	Specification for braille paper
18	IS 11708 : 1986	Specification for hand, mechanical
19	IS 12104 : 1987	Specification for abacus for visually handicapped
20	IS 12152 : 1987	Specification for pocket frame, braille writing
21	IS 12184 : 1987	Specification for stylus for braille writing
22	IS 12439 : 1988	Specification for signature guide for visually impaired
23	IS 12664 (Part 1) : 2003	Artificial limbs - Sach foot for lower extremity prostheses: Part 1 design and dimensions (First Revision)
24	IS 12683 (Part 1) : 1989	Measuring devices for visually impaired persons - Specification: Part 1 scale, general purposes
25	IS 12683 (Part 2) : 1989	Artificial limbs - Measuring devices for visually impaired persons: Part 2 type
26	IS 12683 (Part 3) : 2000	Measuring devices for visually impaired persons - Specification: Part 3 goniometer
27	IS 13017 : 1991	Rehabilitation equipment - Walker rollator - Specification
28	IS 13822 : 1993	Braille duplicating sheet specification
29	IS 13837 : 1993	Braille duplicating machine specification
30	IS 13970 (Part 1) : 2023/ISO 8549-1:2020	Prosthetics and orthotics Vocabulary Part 1: General terms for external limb prostheses and external orthoses First Revision
31	IS 13970 (Part 2) : 2023/ISO 8549-2:2020	Prosthetics and orthotics Vocabulary Part 2: Terms relating to external limb prostheses and wearers of these prostheses First Revision

32	IS 13970 (Part 3) : 2023/ISO 8549-3: 2020	Prosthetics and orthotics Vocabulary Part 3: Terms relating to orthoses First Revision
33	IS 14429 : 1997	Braille shorthand machine - Specification
34	IS 14723 : 1999	Artificial limbs - Knee shin assembly - Specification
35	IS 14879 : 2000	Anterior spinal hyperextension (ASH) brace - Specification
36	IS 15376 (Part 1) : 2003/ISO 8670-1	Ostomy collection bags: Part 1 vocabulary
37	IS 15376 (Part 2) : 2003/ISO 8670-2	Ostomy collection bags: Part 2 requirements and test methods
38	IS/ISO 16021 : 2000	Urine-Absorbing Aids — Basic Principles for Evaluation of Single-Use Adult-Incontinence-Absorbing Aids from the Perspective of Users and Caregivers
39	IS 17034 : 2018	Specification for jaipur foot
40	IS 17063 : 2018	Specification for Rehabilitation Equipment — Rough Terrain Active Wheelchairs, Folding, Rider-I, Adult and Child Size
41	IS 17154 : 2019	Battery operated motorized tricycle - Specification
42	IS 17154 : 2024	Battery Operated Motorized Tricycle - Specification (First Revision)
43	IS 17155 : 2019	Tricycle Single Hand Propelled Right Left Junior Size - Specification First Revision
44	IS 17157 : 2019	Multi utility tricycle - Specification
45	IS 17194 : 2019	Surgical ankle boot with broad toe (Child And Adult Size) - Specification
46	IS 18295 : 2023/ISO 23600:2007	Assistive products for persons with vision impairments and persons with vision and hearing impairments Acoustic and tactile signals for pedestrian traffic lights
47	IS 18296 : 2023/ISO 23599:2019	Assistive products for blind and vision-impaired persons Tactile walking surface indicators
48	IS 18428 (Part 1) : 2023/ISO/TR 11548- 1:2001	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
49	IS 18428 (Part 2) : 2023/ISO TR 11548- 2:2001	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
50	IS 18559 (Part 1) : 2024/ISO 24415-1: 2009	Tips for assistive products for walking Requirements and test methods Part 1: Friction of tips
51	IS 18559 (Part 2) : 2024/ISO 24415-2: 2011	Tips for assistive products for walking Requirements and test methods Part 2: Durability of tips for crutches
52	IS 18560 : 2024/ISO 9999:2022	Assistive products Classification and terminology
53	IS 18651 (Part 1) : 2024/ISO 7176-1:2014	Wheelchairs Part 1: Determination of static stability
54	IS 18651 (Part 2) : 2024/ISO 7176-2:2017	Wheelchairs Part 2: Determination of dynamic stability of electrically powered wheelchairs
55	IS 18651 (Part 3) : 2024/ISO 7176-3:2012	Wheelchairs Part 3: Determination of effectiveness of brakes
56	IS 18651 (Part 4) : 2024/ISO 7176-4:2008	Wheelchairs Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
57	IS 18651 (Part 5) : 2024/ISO 7176-5:2008	Wheelchairs Part 5: Determination of dimensions mass and manoeuvring space
58	IS 18651 (Part 6) : 2024/ISO 7176-6:2018	Wheelchairs Part 6: Determination of maximum speed of electrically powered wheelchairs
59	IS 18651 (Part 7) : 2024/ISO 7176-7:1998	Wheelchairs Part 7: Measurement of seating and wheel dimensions

<b>60</b>	IS 18651 (Part 9) : 2024/ISO 7176-9:2009	Wheelchairs Part 9: Climatic tests for electric wheelchairs
<b>61</b>	IS 18651 (Part 10) : 2024/ISO 7176-10:2008	Wheelchairs Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
<b>62</b>	IS 18651 (Part 11) : 2024/ISO 7176-11:2012	Wheelchairs Part 11: Test dummies
<b>63</b>	IS 18651 (Part 13) : 2024/ISO 7176-13:1989	Wheelchairs Part 13: Determination of coefficient of friction of test surfaces
<b>64</b>	IS 18651 (Part 15) : 2024/ISO 7176-15:1996	Wheelchairs Part 15: Requirements for information disclosure documentation and labelling
<b>65</b>	IS 18651 (Part 19) : 2024/ISO 7176-19:2022	Wheelchairs Part 19: Wheelchairs for use as seats in motor vehicles
<b>66</b>	IS 18653 (Part 1) : 2024/ISO 11199-1: 2021	Assistive products for walking manipulated by both arms Requirements and test methods Part 1: Walking frames
<b>67</b>	IS 18653 (Part 2) : 2024/ISO 11199-2:2021	Assistive products for walking manipulated by both arms - Requirements and test methods Part 2 Rollators
<b>68</b>	IS 18653 (Part 3) : 2024/ISO 11199-3:2005	Walking aids manipulated by both arms Requirements and test methods Part 3: Walking tables
<b>69</b>	IS 18660 : 2024/ISO 19029:2016	Accessible design Auditory guiding signals in public facilities
<b>70</b>	IS 18665 : 2024/ISO 10328:2016	Prosthetics — Structural Testing of Lower-Limb Prostheses — Requirements and Test Methods
<b>71</b>	IS 18831 : 2024/ISO 17966:2016	Assistive products for personal hygiene that support users - Requirements and Methods of Test
<b>72</b>	IS/ISO 21856 : 2022	Assistive products General requirements and test methods
<b>73</b>	IS/ISO 22523 : 2006	External limb prostheses and external orthoses - Requirements and test methods
<b>74</b>	IS/ISO 22675 : 2016	Prosthetics - Testing of ankle - Foot devices and foot units - Requirements and test methods
<b>75</b>	IS 4534 : 1980	Specification for adapter for terminal devices, artificial limbs (First Revision)
<b>76</b>	IS 4535 : 1968	Specification for saw - Grip terminal device for artificial limbs
<b>77</b>	IS 4554 : 1968	Specification for hammers terminal devices, ball peen and claw, for artificial limbs
<b>78</b>	IS 4555 : 1980	Specification for biprong terminal device, draughtsman, for artificial - Limbs (First Revision)
<b>79</b>	IS 4556 : 1968	Specification for typing finger terminal device for artificial limbs
<b>80</b>	IS 4567 : 1968	Specification for pliers terminal device, quick - Grip, for artificial limbs
<b>81</b>	IS 4577 : 1980	Specification for spade - Grip terminal device for artificial limbs (First Revision)
<b>82</b>	IS 4609 : 1980	Specification for pencil - Holding device for artificial limbs (First Revision)
<b>83</b>	IS 4675 : 1968	Specification for light split - Hook device for artificial limbs
<b>84</b>	IS 4677 : 1968	Specification for steering appliance for artificial limbs
<b>85</b>	IS 5015 : 1969	Specification for knife - Terminal device for artificial limbs
<b>86</b>	IS 5143 : 1988	Specification for adjustable axillary crutches (Second Revision)
<b>87</b>	IS 5143 : 2024	Specification for metal forearm crutches (Canadian Pattern) (First Revision)
<b>88</b>	IS 5144 : 1980	Specification for metal forearm crutches (Canadian Pattern) (First Revision)
<b>89</b>	IS 5145 : 1969	Specification for walking sticks
<b>90</b>	IS 5150 : 1969	Specification for rubber tips for crutches and walking sticks

91	IS 5586 : 1970	Specification for metal component for sectional forearm
92	IS 5594 : 1983	Specification for wrist unit, rotary, for hand prosthesis (First Revision)
93	IS 5603 : 1983	Specification for mechanical elbow joint (First Revision)
94	IS 5607 : 1970	Specification for semi - Automatic elbow joint
95	IS 5665 : 1982	Specification for shoulder wheel (First Revision)
96	IS 5745 : 1986	Specification for heel socket and plate for orthosis (First Revision)
97	IS 5796 : 1970	Specification for disc type weight set for physio - Therapy exercisers other than pulley arrangements
98	IS 5809 : 1986	Specification for ankle joint for orthosis (First Revision)
99	IS 5810 : 1986	Specification for knee joint with lock for orthosis (First Revision)
100	IS 5827 : 1982	Specification for paraffin wax bath (First Revision)
101	IS 5956 : 1986	Specification for hip joint with lock for orthosis (First Revision)
102	IS 5963 : 1971	Specification for knee joint without lock for steel orthopaedic calipers
103	IS 5964 : 1971	Specification for round spur for orthopaedic calipers
104	IS 6069 : 1971	Specification for sliding seat exerciser
105	IS 6099 : 1991	Rehabilitation equipment - Invalid walkers with crutches - Specification (Second Revision)
106	IS 6205 : 1982	Specification for stationary cycle exerciser for adults (First Revision)
107	IS 6221 : 1971	Specification for pelvic band for steel orthopaedic calipers and braces
108	IS 6222 : 1971	Specification for thigh band for orthopaedic calipers and braces
109	IS 6223 : 1971	Specification for calf band for orthopaedic calipers and braces
110	IS 6224 : 1980	Specification for tuber band for orthopaedic calipers and braces
111	IS 6275 : 1971	Specification for lower extremity full length brace with joints with locks
112	IS 6302 : 1971	Specification for whirlpool bath
113	IS 6414 : 1972	Specification for parallel walking bars, adult and child sizes, for the handicapped
114	IS 6571 : 1991	Rehabilitation equipment - Wheelchairs, non - Folding, adult size, institutional model - Specification (First Revision)
115	IS 6624 : 1972	Specification for basic hand splint, palmar arch support
116	IS 6625 : 1972	Specification for basic hand splint component
117	IS 6626 : 1972	Specification for basic hand splint, forearm piece
118	IS 6781 : 1972	Specification for staple ankle joint
119	IS 6802 : 1986	Specification for prosthetic hip joint (First Revision)
120	IS 6809 : 1990	Rehabilitation equipment - Fixed height walking frame - Specification (First Revision)
121	IS 6810 : 1990	Rehabilitation equipment - Metal tripod and tetrapod sticks - Specification (First Revision)
122	IS 6812 : 2003	Knee joint, uniaxial for below knee prostheses - Specification (Second Revision)
123	IS 6979 : 1973	Specification for cerebral palsy chair, tubular, institutional model
124	IS 6992 : 1982	Specification for cerebral palsy chair, domestic model (First Revision)
125	IS 6993 : 1973	Specification for pan knee joint

<b>126</b>	IS 6995 : 1973	Specification for cruciform below - Knee joint
<b>127</b>	IS/ISO 7176-26 : 2007	Wheelchairs: Part 26 vocabulary
<b>128</b>	IS 7373 : 2003	Hip disarticulation joint unit for lower limb prosthetic fitments - Specification (Second Revision)
<b>129</b>	IS 7419 : 1983	Requirements for stairs for physical rehabilitation (First Revision)
<b>130</b>	IS 7454 : 1991	Rehabilitation equipment - Wheelchairs, folding, adult size - Specification (First Revision)
<b>131</b>	IS 7454 : 2024	Rehabilitation Equipment " Wheelchairs, Folding, Adult Size" Specification (Second Revision)
<b>132</b>	IS 7924 : 1976	Specification for thigh blocks, wooden
<b>133</b>	IS 8086 : 1991	Rehabilitation equipment - Wheelchairs, folding, junior size - Specification (First Revision)
<b>134</b>	IS 8086 : 2024	Rehabilitation Equipment - Wheelchairs, Folding, Junior Size - Specification (Second Revision)
<b>135</b>	IS 8088 : 2019	Tricycle, hand propelled - specification (First Revision)
<b>136</b>	IS 8492 : 1985	Specification for ankle blocks, wooden (First Revision)
<b>137</b>	IS 8511 : 1985	Specification for valves for suction socket for artificial limbs (First Revision)
<b>138</b>	IS/ISO 8669-2 : 1996	Urine Collection Bags Part 2 Requirements and Test Methods
<b>139</b>	IS 8798 : 1978	Specification for wheel, multipurpose
<b>140</b>	IS 9471 (Part 1) : 1980	Specification for modular lower limb orthotic components: Part 1 stirrups
<b>141</b>	IS 9471 (Part 2) : 1980	Specification for modular lower limb orthotic components: Part 2 stirrups, split
<b>142</b>	IS 9471 (Part 3) : 2024	Modular Lower Limb Orthotic Components" Specification Part 3 Stirrup Plates (First Revision)
<b>143</b>	IS 9471 (Part 3) : 1980	Specification for modular lower limb orthotic components: Part 3 stirrup plates
<b>144</b>	IS 9471 (Part 4) : 2024	Modular Lower Limb Orthotic Components " Specification Part 4 Joint Unit, Ankle (First Revision)
<b>145</b>	IS 9471 (Part 4) : 1980	Specification for modular lower limb orthotic components: Part 4 joint unit, ankle
<b>146</b>	IS 9471 (Part 5) : 1980	Specification for modular lower limb orthotic components: Part 5 joint unit, knee
<b>147</b>	IS 9471 (Part 5/Sec 2) : 2019	Specification for modular lower limb orthotic components: Part 5 joint unit section 2 standard knee
<b>148</b>	IS 9471 (Part 6) : 2024	Modular Lower Limb Orthotic Components - Specification Part 6 Orthotic Hip Joint (Joint Unit, Hip Drop Lock) (First Revision)
<b>149</b>	IS 9471 (Part 6) : 2000	Modular lower limb orthotic components part 6 orthotic hip joint (Joint Unit, Hip Drop Lock) - Specification
<b>150</b>	IS 9471 (Part 7) : 2024	Modular Lower Limb Orthotic Components - Specification Part 7 Orthotic Joint Bars, Ankle and Knee (Upper and Lower) (First Revision)
<b>151</b>	IS 9471 (Part 7) : 2000	Modular lower limb orthotic components - Specification: Part 7 orthotic joint bars, ankle and knee (Upper And Lower)
<b>152</b>	IS 9797 : 1981	Specification for cycle, fret - Saw

**ANNEXURE REFERRED TO IN REPLY TO PART (b) OF LOK SABHA UNSTARRED QUESTION NUMBER NO.3754 FOR ANSWER ON 18.12.2024 REGARDING DEVELOPMENT OF STANDARDS FOR MEDICAL ASSISTIVE TECHNOLOGIES.**  
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Details of Priority List-I (March 2025) are as under:-

<b>Sr No.</b>	<b>Subject</b>
1	PDA closure device / Muscular VSD closure device/ASD closure device
2	Dental Intra oral camera
3	Dental motorised Suction Unit
4	Airway exchange catheter and bougie
5	Endotracheal tube – cuffed, microcuffed tube, laser double lumen and Reinforced tube
6	Bain’s circuit & JR circuit
7	HFNO with cannula
8	NIV, NRB, Venturi Mask & Nebulizer Mask
9	HME Filters
10	Oro + Nasopharyngeal airway
11	Supraglottic devices
12	High Flow Nasal O2 therapy Unit
13	Closed suction catheter
14	Plasma Sterilizer
15	Introducer sheath (Femoral, Radial/Brachial), Mullin sheath, Shuttle sheath
16	Coronary Angiography diagnostic catheters
17	Angiographic Guide Wire (all types)
18	Angiography catheter/ Angioplasty guiding catheter
19	Radiofrequency ablation catheter and connectors
20	steerable guidewires
21	ENT treatment unit
22	Navigation system
23	Blood Gas Analyser
24	Electrolyte Analyzer
25	Chemiluminescence Analyser
26	Hydrogen breath testing device
27	Esophageal impedance manometry
28	Telescope
29	OIU Set
30	Monopolar /Bipolar TURP Set
31	Cannulated Battery Drill/Battery Operated Drill/Micromotor Drill/High Speed Pneumatic Drill/Oscillating Saw with Drill
32	Inflation device
33	Y-connector
34	Manifold



35	Fully Electrically Operated Dental Chair
36	Cervical Traction unit
37	Bicycle ergo meter
38	Tilt table
39	UVR with stand (It is a medical device use for pressure ulcers & wound healing)
40	Infra red with stand (It is a medical device used for pain management )
41	Automatic Anaerobic Jar System
42	CO2 Laser
43	Fluid warmer
44	X-Ray view box
45	Body Composition Monitor
46	Portable X ray Machine
47	HPLC HbA1c analyzer
48	Electrophoresis system
49	Western blot apparatus
50	Automated Identification & Sensitivity system for bacteria & yeast Automated tb culture system-MGIT
51	Fully Automated Blood Culture System
52	Mannequin for skill based training
53	Ultrasonic energy devices
54	Vessel sealing devices
55	Fully Automated Chemiluminescence immunoassay analyser
56	Urine Strip Analyzer

**ANNEXURE-III**

**ANNEXURE REFERRED TO IN REPLY TO PART (b) OF LOK SABHA UNSTARRED QUESTION NUMBER NO.3754 FOR ANSWER ON 18.12.2024 REGARDING DEVELOPMENT OF STANDARDS FOR MEDICAL ASSISTIVE TECHNOLOGIES.**

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Details of Priority List-II (December 2025) are as under:-

<b>Sr No.</b>	<b>Subject</b>
1	PCNL Set
2	Pneumatic Lithoclast
3	Tissue Morcellator
4	Extra Shock Wave Lithotripsy (ESWL)
5	Uro Flow Meter
6	Urodynamic Machine
7	Operating Loupe
8	Hyfrecator
9	Phototherapy chamber
10	Iontophoresis machine
11	Arthroscopy Work Station
12	Single/ Double Bundle ACL Reconstruction Set + PCL Reconstruction
13	CTG Machine
14	Labor Table
15	Fetoscopy Set
16	Epilepsy Monitoring Equipment
17	Transcranial Magnetic Stimulation (Diagnostic & Therapeutic)
18	3D Dental Printers
19	Dental Lasers (including soft tissues)
20	CPM Upper Limb/Lower limb
21	Gait Training Treadmill
22	Cryotherapy Equipment
23	Osmometer
24	Impulse oscillometry
25	Pocket dosimeter
26	Water Phantom/slab phantom/Computed Tomography Dose Index Phantom/Anthropomorphic radiation therapy phantoms
27	Microwave ablation generator with probes.
28	Cryoablation system
29	Interferential therapy unit
30	Thermoablation instrument
31	Cartridge-Based Nucleic Acid Amplification Test
32	HPLC hemoglobinopathies analyser

33	Automated ESR Analyser
34	Platelet Aggregometer
35	Automated semen Analyser
36	Automated Urine and fluid Analyser
37	Tissue embedding station/Automated Rotary microtome
38	Automatic Tissue Processor
39	Cryomicrotome
40	Body bags
41	Grossing station with imaging and documentation
42	Cryosurgical equipment, cryotherapy unit
43	Biopsy punches
44	Dermatoscope
45	Phototherapy machine
46	Wood's lamp
47	ERCP processor and Endoscopy system
48	Endoscopy Reprocessor
49	Endoscopy storage and pH metry system
50	pHmetry system
51	Laparoscopic set with HD camera, Monitor light Source & CO2 Insufflators
52	Meniscal repair Set
53	Bankart repair Set
54	Rotator Cuff repair Set
55	Hysteroscope set with Hysteromat & office hysteroscope
56	Colposcope
57	Micro debrider
58	Nasal Endoscopes
59	Plasma Ablation System (Coblation System)
60	LED head light
61	Flexible Video-Rhino-Laryngoscope (FOL)
62	Camera monitor system for endoscopic sinus surgery
63	Otoendoscopes
64	Microlaryngoscope
65	Pure Tone Audiometer with Speech audiometers
66	Tympanometer
67	Automated otoacoustic emission recorder
68	Automated auditory brain stem recorder
69	Videonystagmography system
70	Evoked Potential system (for Brain Stem Evoked Response audiometry and Auditory steady state responses and vestibular evoked myogenic potentials)
71	Stroboscope
72	Flexible Fibre optic bronchoscope
73	Manometer (in-line for venious pressure measurement)
74	Torque device

75	Physiological pressure transducer
76	Radiolucent ECG electrodes.
77	Embolization coils
78	Microcoil delivery system
79	Reusable pressure transducer plate
80	Disposable ACT tubes
81	Balloon flotation temporary pacemaker lead
82	Mitral Valvuloplasty Single/Double lumen PTMC balloon with/without vent tube
83	Rotational atherectomy catheter
84	Intracoronary intravascular Ultrasound catheter
85	Coronary stent PTFE Graft
86	His bundle pacing system
87	CVP line
88	DVT Pumps with sleeves
89	ACT monitoring machine.
90	Angiojet thrombectomy system.
91	Dialyzer Reprocessing Machine
92	Intra Operative Neuro Monitoring System
93	TMS systems
94	Electronic Balance(it is a medical device used for the patients with neurological balance disorders. )
95	Dental Piezo - Ultrasonic Scaler
96	Dental sand blasting Machine
97	Orthodontic welder
98	Dental Casting Machine
99	Dental Lathe
100	Dental Ceramic furnace
101	Glass Bead Sterilizer
102	Piezo surgical unit
103	Oscillating saws (with all hand piece )
104	Robotic Hand Trainer
105	Dynamic Stair Trainer
106	Active passive trainer
107	Robotic gait trainer
108	Pressure mapping systems (it is a medical device used for the patients with Gait balance disorders. Evaluates pressure distribution and magnitude. )
109	Motion capture systems for gait analysis and movement assessment
110	Fully automated Liquid based cytology system
111	Semenology incubator
112	PCR/Thermal Cycler/Real time PCR/ Digital PCR/Real time quantitative PCR
113	PM Line
114	3-way stop cock
115	Dome kit with flushing system

116	coronary microcatheter
117	E.P. Catheters (multipolar and uni directional and bi-directional)
118	Mother and child catheter assembly
119	CSE Set
120	Epidural Set (Adult and Paediatric)
121	Spinal Needle (Adult and Paediatric)
122	ETO sterilisation system
123	Physiodispenser
124	Dialysis Chair
125	Cell Separator (Apheresis machine)
126	Goggles
127	Face shield
128	Hydraulic Bed
129	Anti- shock garment
130	PMO lines and PICC line (PICC- it is a medical device called as Peripherally inserted central catheters-Central venous line for giving fluids/taking blood samples. PMO- Pressure Monitoring line , It is a medical device acts as an intermediary device between syringe pump and iv cannulae )
131	Angiography Machine: Monoplane / Bi-plane Digital Substraction Angiography Machine
132	TEG machine (Thromboelastography - method of testing the efficiency of blood coagulation. It is a medical device.)
133	Continuous Renal Replacement Therapy machine
134	Poly somnography machine
135	Cobalt 60 Teletherapy Machine
136	Tomotherapy
137	Robotic DSA system.
138	CO2 angiography system.
139	Xenon inhalation system for CBF
140	Laser Scanning unit (Used in Pain management can be called as scanning laser therapy equipment)
141	Continuous Renal Teplacement Therapy (CRRT) Machine
142	Lase alignment tool
143	Winston lutz test tool for SRS and SBRT
144	Radiation Field alignment test tools with radiopaque markers
145	Polysomnography
146	Radiovisiography Machine (RVG)
147	Orthopantomogram Machine (OPG)
148	Tissue microarray System
149	Fully Automated ImmunoAssay Analyser (IIF based) for ANA Screening
150	Fully Automated Immunostainer
151	Platelet function testing system
152	CBC Counter

153	Automated Hematology Analyser
154	Automated coagulation analyser (Fully automated & semi automated)
155	Microarray/ similar technology for rapid syndrome management
156	Quick cool histology
157	Fully Automated high risk HPV DNA detection & genotyping system
158	DNA sequencer system

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