

	Company Name: የኢትዮጵያ የደረጃዎች ኤጀንሲ ETHIOPIAN STANDARDS AGENCY	Document No.: OF/ESA/SDD/034
	Title: ES DRAFT UPLOAD REQUEST FORM FOR PUBLIC COMMENTS	Issue No.: 3

This form is used to maintain uniformity and consistency in uploading the list of draft documents for the development of Ethiopian standards for public comment.

1. The draft documents submitted for uploading shall be displayed using the table shown below:-

ESA invites the public to comment on the following draft Ethiopian standards :-

Field	Title	Number of Standards under development				Total
		New	Reaffirmation	Revision	Withdrawal	
EHS	Evaluation and routine testing in medical imaging departments-Part 2-3: Constancy tests-Darkroom safe light conditions				✓	73
	Protective devices against diagnostic medical x-radiation				✓	
	Tracheal tubes - Part 4: Cole type				✓	
	Anaesthetic and respiratory equipment tracheostomytubes				✓	
	Anaesthetic and respiratory equipment— Tracheostomy tubes—Part 3:Paediatric tracheostomy tubes				✓	
	Surgical instruments - Non-cutting,articulated instruments – General requirements & test methods		✓			
	Neurosurgical implants — Sterile, single-use hydrocephalus shunts and components		✓			
	Implants for surgery — Components for partial and total knee joint prostheses Part 1: Classification, definitions and designation of dimensions		✓			
	Anaesthetic and respiratory equipment Laryngoscopes for tracheal intubation		✓			
	Anaesthetic and respiratory equipment Heat and moisture exchangers (HMEs) for humidifying respired gases in humans Part1:HMEs for use with minimum tidal volumes of 250ml		✓			
	Anaesthetic and respiratory equipment, Heat and moisture exchangers (HMEs) for humidifying respired gases in humans- Part2HMEs for use with tracheostomized patientshaving minimum tidal volumes of 250ml		✓			
	Implants for surgery-Malleable wires for use as sutures and other surgical applications		✓			
	Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with		✓			

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	cylinder valves					
	Pressure regulators for use with medical gases — Part 4: Low-pressure regulators		✓			
	Lung ventilators for medical use - Part 3: Particular requirements for emergency and transport ventilators		✓			
	Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators		✓			
	Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 5: Gas-powered emergency resuscitators		✓			
	Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 6: Home-care ventilatory support devices		✓			
	Prefilled syringes -Part 2:Plunger stoppers for dental local anaesthetic cartridges		✓			
	Respiratory equipment — Infant monitors — Particular requirements		✓			
	Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects		✓			
	Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time forced expired volumes in humans		✓			
	Anaesthetic and respiratory equipment —User- applied labels for syringes containing drugs used during anaesthesia — Colours, design and performance		✓			
	Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment	✓				
	Medical electrical equipment – Part 2-71: Particular requirements for the basic safety and essential performance of functional near-infrared spectroscopy (NIRS) equipment	✓				
	Anaesthetic and respiratory equipment — Conical connectorPart 1: Part 1- Cones and sockets			✓		
	Anaesthetic and respiratory equipment Conical connectors Part 2: Screw-threaded weight-bearing connectors			✓		
	Anaesthetic v aporizers –Agent specific filling systems			✓		
	Anaesthetic and respiratory equipment — Tracheal tubes and connectors			✓		
	Anaesthetic and respiratory equipment —			✓		



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	Oropharyngeal airways					
	Anaesthetic and respiratory equipment- Tracheostomy tubes andconnectors			✓		
	Implants for surgery — Cardiac pacemaker 2: Reporting of clinical performance of populations of pulse generators or leads			✓		
	Implants for surgery — Cardiac Pacemakers 3: Low-profile connectors (IS-1) for implantable pacemakers			✓		
	Medical devices — Application of risk management to medical devices			✓		
	Dentistry-Mixing machines for- Dental amalgam	✓				
	Dentistry-Stationary dental units and dental patient chairs-Part 1: General requirements	✓				
	Dentistry-Dental units-Part 2:Air, water, suction and wastewater systems	✓				
	Extracorporeal systems for blood purification.—Part 1:Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators	✓				
	Extracorporeal systems for blood purification —PExtrac2: orporeal blood circuit for haemodialysers, haemodiafilters and haemofilte rs	✓				
	Extracorporeal systems for blood purification.—Part 3 Plasmafilte rs	✓				
	Suction catheters for use in the respiratory tract			✓		
	Terminal units for medical gas pipeline Part 1: systems —Terminal units for use with compressed medical gases and vacuum			✓		
	Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems		✓			
	Medical suction equipment- Part 1: Electrically powered suction equipment			✓		
	Medical suction equipment-Part-3 Suction equipment powered from a vacuum or positive pressure gas source			✓		
	Pressure regulators for use with medical Part 1: gases —Pressure regulators and pressure regulators with flow-metering devices	✓				
	Pressure regulators for use with medical gases —Part 2:Manifold and line pressure regulators	✓				
	Prefilled syringes —Part 1:Glass cy linders for			✓		



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	dental local anaesthetic cartridges					
	Gas mixers for medical use — Stand-alone gas mixers	✓				
	Medical supply units	✓				
	Quality of dialysis for haemodialysis and related therapies	✓				
	Lasers and laser-related equipment — Test method and classification for the laser resistance of surgical drapes and/or patient protective covers — Primary ignition, penetration, flame spread and secondary ignition			✓		
	Medical Concentrates for haemodialysis and related therapies			✓		
	Water for haemodialysis and related therapies			✓		
	Tracheal tubes designed for laser surgery — Requirements for marking and accompanying information			✓		
	Medical electrical equipment-Part 2-67: Particular requirements for basic safety and essential performance of oxygen conserving equipment			✓		
	Medical electrical equipment – Part 2-72: Particular requirements for the basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients	✓				
	Medical electrical equipment-Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment			✓		
	Use and handling of medical devices covered by the scope of ISO/TC 84- Risk assessment on mucocutaneous blood exposure	✓				
	Implants for surgery-Cardiac pacemakers Part 3:Low-profile connectors (IS-1) for implantable pacemakers			✓		
	Ophthalmic optics — Uncut finished spectacle lenses — Part 1: Specifications for single-vision and multifocal lenses			✓		
	Ophthalmic optics — Uncut finished spectacle lenses —Part 2: Specifications for power-variation lenses			✓		
	Ophthalmic optics — Uncut finished spectacle			✓		

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	enses —Part 3: Transmittance specifications and test methods				
	nstrumentation for use in association with non-active surgical implants — General requirements			✓	
	Inhalational anaesthesia systems —Draw-over anaesthetic systems			✓	
	Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans			✓	
	Anaesthetic and respiratory equipment — Nebulizing systems and components			✓	
	Small-bore connectors for liquids and gases in healthcare applications —Part 3: Connectors for enteral applications	✓			
	Small bore connectors for liquids and gases in healthcare applications —Part 6: Connectors for neuraxial applications	✓			
	ectrical equipment — Part 2-12: Particular requirements forbasic safety and essential performance of critical care ventilators	✓			
	Medical electrical equipment —Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors			✓	
	Medical electrical equipment —Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperaturemeasurement			✓	
	Medical electrical equipment — Part 2-13: Particular requirements for basic safetyand essential performance of an anaesthetic workstation	✓			

The deadline for comment receiving is 24December 2018

Comments can be submitted using the following addresses:-

E-mail...tesfayey@ethiostandards.org/melkamtesfa@gmail.com

Fax 0116460880/81

Tel 0116460567

Ballot form is attached

2. Document transfer:

A/ Request presented by Tesfaye Yakob

From Environment, Health & Safety standards development Team.

Date ----- Signature -----

B) Director's Approval.....

Date.....Signature.....

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C/ Request received by -----

Format ----- Date ----- Signature ----- **Notes:-**

A/ Documents without water mark and signature shall not be uploaded.

B/ Documents shall be removed immediately following the deadline fixed for comments receiving

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