

## HealthCare Standards Consultative Committee Current Documents out for vote and comment.

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### a) SC 1 Dentistry: (Following the work of CEN TC 55 and ISO TC 106)

Document Title and Details	Close Date
DIS ISO/TC 106/SC 2 ISO 13078 Dentistry - Dental furnace - Test method for temperature measurement with separate thermocouple	2011-12-28
SR ISO/TC 106/SC 2 ISO 15854:2005 Dentistry - Dental furnace - Test method for temperature measurement with separate thermocouple	2011-12-15
SR ISO/TC 106/SC 2 ISO 20795-1:2008 Dentistry Casting and base plate waxes	2011-12-15
SR ISO/TC 106 ISO 7405:2008 (Ed 2) Dentistry -- Evaluation of biocompatibility of medical devices used in dentistry	15/03/2012
ISO/TC 106/SC 2 ISO/DIS 6873 (Ed 3) Dentistry -- Gypsum products	17/04/2012
CEN TC 55 prEN ISO 1797-3 Dentistry - Shanks for rotary instruments - Part 3: Shanks made of ceramics (ISO/DIS 1797-3:2011)	2012-03-27
CEN TC 55 prEN 10323 Dentistry - Bore diameters for rotary instruments such as discs and wheels (ISO/DIS 10323:2011)	2011-11-30
CEN TC 55 EN ISO 13397-2:2005/prA1 Dentistry - Periodontal cures, dental scalers and excavators - Part 2: Periodontal cures of Gr-type - Amendment 1: Colour coding (ISO 13397-2:2005/DAM 1:2011)	2012-04-24

### a) SC 2 In Vitro Diagnostics: (Following the work of CEN TC 140 and ISO TC 212)

Document Title and Details	Close Date
ISO TC 212 ISO/DIS 16256 Clinical laboratory testing and in vitro diagnostic test systems -- Reference method for testing the in vitro activity of antimicrobial agents against yeast of fungi involved in infectious diseases	08/02/2012

### b) SC 3 Ophthalmics: (Following the work of CEN TC170 and ISO TC172)

Document Title and Details	Close Date
SR ISO/TC 172/SC 7 ISO 14729:2001 (vers. 2) Ophthalmic optics - - Contact lens care products -- Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses	2011-12-15
SR ISO/TC 172/SC 7 ISO 24157:2008 Ophthalmic optics and instruments -- Reporting aberrations of the human eye	2011-12-15
ISO/TC 172/SC 3 ISO/DIS 9211-4 (Ed 3) Optics and photonics -- Optical coatings -- Part 4: Specific test methods	10/03/2012
ISO/TC 172/SC 7 ISO/DIS 8980-3 (Ed 3) Ophthalmic optics -- Uncut finished spectacle lenses -- Part 3: Transmittance specifications and test methods	13/03/2012

ISO/TC 172/SC 7 ISO/DIS 9394 (Ed 3 Ophthalmic optics -- Contact lenses and contact lens care products -- Determination of biocompatibility by ocular study with rabbit eyes)	2012-02-29
ISO/TC 172/SC 7 ISO 11979-7:2006/FDAmD 1 Ophthalmic implants -- Intraocular lenses -- Part 7: Clinical investigations -- Amendment 1	03/01/2012
ISO/TC 172/SC 7 ISO/DIS 14889 (Ed 3) Ophthalmic optics -- Spectacle lenses -- Fundamental requirements for uncut finished lenses	20/03/2012
ISO/TC 172/SC 7 ISO/DIS 22665 Ophthalmic optics and instruments - Instruments to measure axial distances in the eye	2012-03-13
ISO/TC 172/SC 7 ISO/CD 10938.2 Ophthalmic instruments - General-purpose clinical visual acuity charts and associated chart projectors	2012-02-06
ISO/TC 172/SC 7 ISO/CD 11979-2.2 Ophthalmic implants -- Intraocular lenses -- Part 2: Optical properties and test methods	2012-02-06
ISO/TC 172/SC 7 ISO/CD 11979-7.2 Ophthalmic implants -- Intraocular lenses -- Part 7: Clinical investigations	2012-02-06
SR ISO/TC 172/SC 7 ISO 8429:1986 (vers 5) Optics and optical instruments -- Ophthalmology -- Graduated dial scale	2011-12-15
DIS ISO/TC 172/SC 7 ISO/DIS 10685-2 Ophthalmic optics -- Spectacle frames and sunglasses electronic catalogue and identification -- Part 2: Commercial information	2012-01-04
DIS ISO/TC 172/SC 7 ISO/DIS 10685-3 Ophthalmic optics -- Spectacle frames and sunglasses electronic catalogue and identification -- Part 3: Technical information	2012-01-04
DIS ISO/TC 172/SC 7 ISO/DIS 11979-1 (Ed 3) Ophthalmic implants -- Intraocular lenses -- Part 1: Vocabulary	2012-01-11
DIS ISO/TC 172/SC 7 ISO/DIS 11979-3 (Ed 3) Ophthalmic implants -- Intraocular lenses -- Part 3: Mechanical properties and test methods	2012-01-11
SR ISO/TC 172/SC 7 ISO 11979-4:2008 (Ed 2) Ophthalmic implants -- Intraocular lenses -- Part 4: Labelling and information	2011-12-15
DIS ISO/TC 172/SC 7 ISO 11979-4:2008/DAmD 1 Ophthalmic implants -- Intraocular lenses -- Part 4: Labelling and information -- Amendment 1	2012-01-11
ENQ CEN TC 170 PrEN ISO 11979-1 Ophthalmic implants -- Intraocular lenses -- Part 1: Vocabulary (ISO/DIS 11979-1:2011)	2012-01-04
ENQ CEN TC 170 PrEN ISO 11979-3 Ophthalmic implants -- Intraocular lenses -- Part 3: Mechanical properties and test methods (ISO/DIS 11979-3:2011)	2012-01-04

**SC 4 Non Active Devices: (Following the work of CEN TC205 and ISO TC076, 084, 157)**

Document Title and Details	Close Date
ISO TC 76: SR ISO 8362-5:2008 (Ed 2) Injection containers and accessories -- Part 5: Freeze drying closures for injection vials	2012-03-15
ISO TC 76: SR ISO 8362-2:2008 (Ed 2) Injection containers and accessories -- Part 2: Closures for injection vials	2012-03-15
ISO TC 76: ISO/FDIS 1135-4 (Ed 5) Transfusion equipment for medical use -- Part 4: Transfusion sets for single use	2012-02-03
ISO TC 76: SR ISO 1135-3:1986 (vers 5) Transfusion equipment for medical use -- Part 3: Blood-taking set	2011-12-15
ISO TC 76: SR ISO 3826-2:2008 Plastics collapsible containers for	2011-12-15

human blood and blood components -- Part 2: Graphical symbols for use on labels and instruction leaflets	
ISO TC 76: SR ISO 8362-3:2001 (Ed 2, vers 2) Injection containers and accessories -- Part 3: Aluminium caps for injection vials Plastics collapsible containers for human blood and blood components -- Part 2: Graphical symbols for use on labels and instruction leaflets	2011-12-15
ISO/TC 84 ISO/DIS 10555-1 (Ed 2) Intravascular catheters -- Sterile and single-use catheters -- Part 1: General requirements	29/02/2012
ISO/TC 84 ISO/DIS 10555-3 (Ed 2) Intravascular catheters -- Sterile and single-use catheters -- Part 3: Central venous catheters	29/02/2012
ISO/TC 84 ISO/DIS 10555-4 (Ed 2) Intravascular catheters -- Sterile and single-use catheters -- Part 4: Balloon dilatation catheters	06/03/2012
ISO/TC 84 ISO/DIS 10555-5 (Ed 2) Intravascular catheters -- Sterile and single-use catheters -- Part 5: Over-needle peripheral catheters	06/03/2012
ISO/TC 84 ISO TC 84 N770 NWIP revision of ISO 9626 ISO TC 84 N770 NWIP revision of ISO 9626.pdf	13/12/2011
ISO/TC 84 ISO TC 84 N771 NWIP on the Revision of ISO 7864 ISO TC 84 N771 NWIP on the Revision of ISO 7864	13/12/2011
ISO/TC 84 ISO TC 84 N772 ISO TC 84 N772 Call for experts for Work item study group on Bolus injection	01/12/2011
ISO/TC 84 ISO TC 84 N776 NWIP Revision of ISO 8537 ISO TC 84 N776 NWIP Revision of ISO 8537	19/12/2011
ISO/TC 84 ISO TC 84 N777 NWIP Revision of ISO 595-2 ISO TC 84 N775 NWIP Revision of ISO 595-2	19/12/2011
ISO/TC 84 ISO/CD 10555-2 Sterile, single-use intravascular catheters -- Part 2: Angiographic catheters	15/01/2012
ISO/TC 84 ISO/TC 84 N773 ISO TC 84 N773 Call for experts for Work Item Study Group - Visually-Impaired	01/12/2011
ISO/TC 84 ISO/TC 84 N774 ISO TC 84 N774 Call for experts for Work item study group on possible revision of ISO 11608-4	01/12/2011
ISO/TC 84 ISO/TC 84 N778 ISO TC 84 N778 NWIP 10555-2 Angiographic catheters.	15/01/2012
ISO/TC 84 ISO/TC 84 N783 ISO TC 84 N783 PWI Mechanically Active catheters	31/12/2011
SR CEN TC 205 <b>Systematic Review of EN 1060-3:1997+A2:2009</b> Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems	2012-03-20
SR CEN TC 205 <b>Systematic Review of EN 12022:1999</b> Blutgasaustauscher???	2012-03-20
SR CEN TC 205 <b>Systematic Review of EN 12439:1998</b> Sterile rectal catheters for single use	2012-03-20
SR CEN TC 205 <b>Systematic Review of EN 12470-1:2000+A1:2009</b> Clinical thermometers - Part 1: Metallic liquid-in-glass thermometers with maximum device	2012-03-20
SR CEN TC 205 <b>Systematic Review of EN 12470-2:2000+A1:2009</b> Clinical thermometers - Part 2: Phase change type (dot matrix) thermometers	2012-03-20
SR CEN TC 205 <b>Systematic Review of EN 12470-3:2000+A1:2009</b> Clinical thermometers - Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device	2012-03-20
SR CEN TC 205 <b>Systematic Review of EN 12470-</b>	2012-03-20

<b>4:2000+A1:2009</b> Clinical thermometers - Part 4: Performance of electrical thermometers for continuous measurement	
SR CEN TC 205 <b>Systematic Review of EN 1283:1996</b> Haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and their extracorporeal circuits	2012-03-20
SR CEN TC 205 <b>Systematic Review of EN 13726-1:2002</b> Test methods for primary wound dressings - Part 1: Aspects of absorbency	2012-03-20
SR CEN TC 205 <b>Systematic Review of EN 13726-2:2002</b> Test methods for primary wound dressings - Part 2: Moisture vapour transmission rate of permeable film dressings	2012-03-20
SR CEN TC 205 <b>Systematic Review of EN 13867:2002+A1:2009</b> Concentrates for haemodialysis and related therapies	2012-03-20
SR CEN TC 205 <b>Systematic Review of EN 13868:2002</b> Catheters - Test methods for kinking of single lumen catheters and medical tubing	2012-03-20
SR CEN TC 205 <b>Systematic Review of EN 1615:2000</b> Enteral feeding catheters and enteral giving sets for single use and their connectors - Design and testing 05	2012-03-20
SR CEN TC 205 <b>Systematic Review of EN 1616:1997</b> Sterile urethral catheters for single use	2012-03-20
SR CEN TC 205 <b>Systematic Review of EN 1617:1997</b> Sterile drainage catheters and accessory devices for single use	2012-03-20
SR CEN TC 205 <b>Systematic Review of EN 1618:1997</b> Catheters other than intravascular catheters - Test methods for common properties	2012-03-20
SR CEN TC 205 <b>Systematic Review of EN 1644-1:1997</b> Test methods for nonwoven compresses for medical use - Part 1: Nonwovens used in the manufacture of compresses	2012-03-20
SR CEN TC 205 <b>Systematic Review of EN 1644-2:2000</b> Test methods for nonwoven compresses for medical use - Part 2: Finished compresses	2012-03-20
SR CEN TC 205 <b>Systematic Review of EN 1707:1996</b> Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings	2012-03-20

**d) SC 5 Respiratory and Anaesthesia: (Following the work of CEN TC 215 and ISO TC121)**

Document Title and Details	Close Date
SR ISO TC 121 SC 2: <b>ISO 5364:2008 (Ed 4)</b> Anaesthetic and respiratory equipment -- Oropharyngeal airways	2011-12-15
SR ISO TC 121 SC 2: ISO 16628:2008 Tracheobronchial tubes -- Sizing and marking	2012-03-15
ISO TC 121 SC 6: ISO 7396-1:2007/DAMd 3 Medical gas pipeline systems -- Part 1: Pipeline systems for compressed medical gases and vacuum -- Amendment 3:	2012-03-06
ISO TC 121 SC 6: ISO TC 121/SC 6 N 935 Medical gas pipeline systems - Essential safety requirements for tubes intended for compressed medical gases and vacuum in medical gas pipeline systems, anaesthetic gas scavenging systems and plume evacuation systems	02/12/2011
ISO TC 121 SC 6: I ISO/WD 10083 SO/WD 10083 (No document)	28/01/2012
ISO TC 121 SC 6: N 952 ISO/WD 7396-1, Medical gas pipeline	17/02/2012

systems - Part 1: Pipeline systems for compressed medical gases and vacuum	
ISO TC 121 SC 6: N 952, ISO/WD 7396-1 Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum	17/02/2012
NP ISO TC 121 SC 6 <b>ISO TC 121/SC 6 N 935</b> Medical gas pipeline systems - Essential safety requirements for tubes intended for compressed medical gases and vacuum in medical gas pipeline systems, anaesthetic gas scavenging systems and plume evacuation systems	2011-12-02

**e) SC 6 Implants: (Following the work of CEN TC 285 and ISO TC 150, 170)**

Document Title and Details	Close Date
CEN TC 285 C440/2011 Adoption of a new work item – ISO/TS 12417 NWIP 'Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products'	2011-11-30
ISO/TC 150/SC 6 ISO/DIS 14708-7 Implants for surgery -- Active implantable medical devices -- Part 7: Particular requirements for cochlear implant systems	2012-03-31
ISO/TC 150/SC 6 ISO TC 150/SC 6 N 252 New work item proposal: ISO 27186:2010/A1, Active implantable medical devices - Four-pole connector system for implantable cardiac rhythm management devices - Dimensional and test requirements	13/01/2012

**f) SC 7 Orthopaedic Implants: (Following the work of CEN TC 285 and ISO TC 168)**

Document Title and Details	Close Date
DIS ISO/TC 168 ISO 10328:2006/DAMd 1 Prosthetics -- Structural testing of lower-limb prostheses -- Requirements and test methods -- Amendment 1	2012-03-15
DIS ISO/TC 168 ISO 22675:2006/DAMd 1 Prosthetics -- Testing of ankle-foot devices and foot units -- Requirements and test methods -- Amendment 1	2012-03-27
SR ISO/TC 168 ISO 29783-1:2008 Prosthetics and orthotics -- Vocabulary -- Part 1: Normal gait CRC	2012-03-15
SR ISO/TC 168 ISO 29782:2008 Prostheses and orthoses -- Factors to be considered when specifying a prosthesis for a person who has had a lower limb amputation	2012-03-15
SR ISO/TC 168 ISO 29781:2008 Prostheses and orthoses -- Factors to be included when describing physical activity of a person who has had a lower limb amputation(s) or who has a deficiency of a lower limb segment(s) present at birth	15/03/2012

**g) SC 8 Sterilisers for Medical Purpose: (Following the work of CEN TC 102 and ISO TC 198)**

Document Title and Details	Close Date
CEN TC 216 prEN 14476 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of viricidal activity of chemical disinfectants and antiseptics used in human medicine -	2012-04-24

Test method and requirements (phase 2, step 1)	
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**h) SC 9 Sterilisation: (Following the work of CEN TC 204, 195, 243 and ISO TC 198, 209)**

Document Title and Details	Close Date
SR ISO/TC 198 <b>ISO 15882:2008</b> Sterilization of health care products -- Chemical indicators -- Guidance for selection, use and interpretation of results	2011-12-15
ISO/TC 198 ISO/DIS 11135 (Ed 2 Sterilization of health-care products -- Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	15/02/2012
ISO/TC 198 ISO 13408-1:2008/DAmD 1 Aseptic processing of health care products -- Part 1: General requirements -- Amendment 1	29/02/2012
ISO/TC 198 ISO 11607-1:2006/CD Amd 1 Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems -- Amendment 1	27/12/2011
ISO/TC 198 ISO 11607-2:2006/CD Amd Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes -- Amendment 1	27/12/2011
ISO/TC 198 ISO 13408-6:2005/CD Amd 1 Aseptic processing of health care products -- Part 6: Isolator systems -- Amendment 1	29/12/2011
ISO/TC 198 ISO/DTS 16775.2 Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2	25/01/2012
SR ISO/TC 122/SC 3 <b>ISO 8474:1986 (vers 5)</b> Packaging -- Complete, filled transport packages -- Water immersion test	2011-12-15
SR ISO/TC 122/SC 3 <b>ISO 13355:2001 (vers 2)</b> Packaging -- Complete, filled transport packages and unit loads -- Vertical random vibration test	2012-03-15

**i) SC10 Horizontal Standards: (Following the work of CEN TCs 206, 257, 258, 316, CLC TF3, ABHS and ISO TCs 194, 210)**

Document Title and Details	Close Date
SR ISO TC 194 <u>ISO 10993-14:2001 (vers 2 Biological evaluation of medical devices -- Part 14: Identification and quantification of degradation products from ceramics)</u>	2012-01-04
SR ISO TC 194 <u>ISO 10993-15:2001 (vers 2) Biological evaluation of medical devices -- Part 15: Identification and quantification of degradation products from metals and alloys</u>	2011-12-15
DIS ISO TC 194 <u>ISO/DIS 10993-3 (Ed 3) Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity</u>	2011-12-15
SR ISO TC 194 ISO 10993-7:2008 (Ed 2) <u>Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals</u>	2012-03-15
SR ISO TC 210 ISO 594-1:1986 (vers 5) Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 1: General requirements	2012-03-15
ISO TC 210 DTS ISO/TS 19218-1:2011/CD Amd 1 – Examples Medical devices -- Hierarchical coding structure for adverse events -- Part 1: Event-type codes -- Amendment 1	2011-12-13

**j) SC 12 Services (Provisional): (Following the work of CEN CHESSES and CEN TC 362 and 328)**

Document Title and Details	Close Date
<b>No documents under development at moment</b>	
CEN TC 362 prEN 15224 Health care services - Quality management systems - Requirements based on EN ISO 9001:2008 DAV 2013-01	

**k) SC 13 Cleanrooms: (Following the work of ISO TC 209)**

Document Title and Details	Close Date
SR ISO/TC 209 ISO 14644-4:2001 (vers 2) Cleanrooms and associated controlled environments -- Part 4: Design, construction and start-up	2011-12-15
ISO/TC 209 ISO/DIS 14644-8 (Ed 2) Cleanrooms and associated controlled environments -- Part 8: Classification of air cleanliness by chemical concentration	15/02/2012
ISO/TC 209 NWIP N235 Assessment of suitability of equipment and materials for cleanrooms	10/02/2012