Working documents for ISO/TC 210

2015 年 1 月 23 日現在

文書 No.	タイトル	Current Stage and registration date
ISO/IEC Guide 63	Guide to the development and inclusion of safety aspects in International Standards for medical devices	CD (committee draft) approved for registration as DIS (Draft international standard) 2014-11
ISO/DIS 13485	Medical devices – Quality management systems – Requirements for regulatory purposes	Report circulated (decision for new DIS ballot) 2014-09 （注:本文を参照のこと）
ISO/DIS 15223-1	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements	DIS approved for registration as FDIS (Final DIS) 2014-11
ISO/CD 15225	Medical devices – Quality management – Medical device nomenclature data structure	CD ballot initiated 2014-11
ISO/DIS 16142-1	Medical devices – Recognized essential principles of safety and performance of medical devices -- Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards	DIS approved for registration as FDIS (Final DIS) 2014-11
ISO/NP 16142-2	Medical devices – Recognized essential principles of safety and performance of medical devices -- Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards	New project approved 2013-05
ISO/DIS 18250-3	Connectors for reservoir delivery systems for healthcare applications – Part 3: Enteral applications	Close of DIS voting 2014-12
ISO/DIS 18250-8	Connectors for reservoir delivery systems for healthcare applications -- Part 8: Citrate-based anticoagulant solution for apheresis applications	DIS ballot initiated 2014-10
ISO/NP 19081	Connectors for citrate-based anticoagulant solution reservoirs for apheresis	New project approved 2013-08
IEC 62304:2006/DAmd 1	Application of risk management for IT-networks incorporating medical devices Part 2-8: Application guidance - Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2	Close of DIS voting 2014-07
IEC/FDIS 62366-1	Medical devices -- Part 1: Application of usability engineering to medical devices	FDIS ballot initiated 2014-12
ISO/AWI TR 80002-2	Medical device software - Part 2: Validation of software for regulated processes	New project registered in work programme 2013-02

ISO/CD 80369-1	Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements	Close of CD voting 2014-12
ISO/CD 80369-2	Small bore connectors for liquids and gases in healthcare applications -- Part 2: Connectors for breathing systems and driving gases applications	Close of CD voting 2012-06
ISO/DIS 80369-3.2	Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications	Close of 2nd DIS voting 2014-11
IEC/DIS 80369-5	Small-bore connectors for liquids and gases in healthcare applications – Part 5: Connectors for limb cuff inflation applications	Close of DIS voting 2014-04
ISO/DIS 80369-6	Small bore connectors for liquids and gases in healthcare applications – Part 6: Connectors for neuraxial applications	DIS ballot initiated 2014-09
ISO/DIS 80369-7	Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications	DIS approved for registration as FDIS 2014-11
ISO/FDIS 80369-20	Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods	FDIS ballot initiated 2014-12