

中国生物医学工程学会

中国生物医学工程学会团体标准公告

Chinese Society Of Biomedical Engineering

Announcement for Standards

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No.1 2021 (No.8 in total)

中国生物医学工程学会批准《超声诊断设备可靠性试验方法》(T/CSBME 024-2020)、《医疗设备可靠性管理规范》(T/CSBME 025-2020)、《肌红蛋白定量测定试剂(盒)(荧光免疫层析法)》(T/CSBME 026-2020)、《肌酸激酶同工酶(CKMB)定量测定试剂(盒)(荧光免疫层析法)》(T/CSBME 027-2020)、《心肌肌钙蛋白 I 定量测定试剂(盒)(荧光免疫层析法)》(T/CSBME 028-2020)、《在用腹膜透析设备质量控制指南》(T/CSBME 029-2020)、《定制式增材制造膝关节矫形器临床评价技术规范》(T/CSBME 030-2020)、《经食道超声探头消毒及存储规范》(T/CSBME 031-2020)、《医用四臂聚乙二醇琥珀酰亚胺戊二酸酯技术要求》(T/CSBME 032-2020)、《医用电气设备故障模式、影响及危害性分析(FMECA)方法》(T/CSBME 033-2020)、《X 射线计算机体层摄影(CT)系统可靠性设计规范》(T/CSBME 034-2020)、《磁共振成像系统可靠性设计规范》(T/CSBME 035-2020)、《医用电气设备环境剖面参数指南》(T/CSBME 036-2020)共 13 项团体标准, 现予公告。

The CSBME standards for Reliability test methods for ultrasonic diagnostic equipment (T/CSBME 024-2020), Reliability Management System of Medical Equipment (T/CSBME 025-2020), Myoglobin Quantitative Assay (Kit) (fluorescence immunochromatography) (T/CSBME 026-2020), Creatin Kinase Isoenzyme (CKMB) Quantitative Assay (kit) (fluorescence immunochromatography) (T/CSBME 027-2020), Cardiac troponin-I quantitative Assay (kit) (fluorescence immunochromatography) (T/CSBME 028-2020), Quality control guidelines for peritoneal dialysis equipment in using (T/CSBME 029-2020), Clinical evaluation specification of custom additive manufacturing knee orthosis (T/CSBME 030-2020), Specification for disinfection and storage of transesophageal echocardiography probe (T/CSBME 031-2020), Technical requirements for raw materials of medical four-arm polyethylene glycol succinimide glutarate (T/CSBME 032-2020), Guidelines for Failure Mode Effects and Criticality Analysis of Medical Electrical Equipment (T/CSBME 033-2020), Specification for reliability design of X-ray Computed Tomography (CT) system (T/CSBME 034-2020), Specification for reliability design of Nuclear Magnetic Resonance Imaging system (T/CSBME 035-2020), Guidelines for Environmental Profile Parameters of Medical Electrical Equipment (T/CSBME 036-2020), were approved by the Chinese Society Of Biomedical Engineering, and now they are effective.

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