

Medicines

The Medical Devices Agency

Notice is hereby given that the following Standards are deemed to be "relevant national standard(s)" for the purposes of the Medical Devices Regulations 1994, the Active Implantable Medical Devices Regulations 1992 and the In Vitro Diagnostic Medical Devices Regulations 2000.

THE MEDICAL DEVICES REGULATIONS 1994 (SI NO. 3017)

Standard Number	Official Journal reference no.	Title	BS Adoptions
CEN EN 455-3: 1999	OJ2000/C293/06	Medical gloves for single use – Part 3: Requirements and testing of biological evaluation.	BSEN 455-3: 2000
CEN EN 737-2 Amendment 1	OJ2000/C293/06	Medical gas pipeline systems – Part 2: Anaesthetic gas scavenging disposal systems – Basic requirements.	BSEN 737-2: 1998 (Amendment incorporated)
CEN EN737-3 Amendment 1	OJ2000/C293/06	Medical gas pipeline systems – Part 3: Pipelines for compressed medical gases and vacuum.	BSEN 737-3: 2000
CEN EN 738-2: 1998	OJ2000/C293/06	Medical regulators for use with, medical gases – Part 2: Manifold and line pressure regulators.	BSEN 738-2: 1999
CEN EN 738-3: 1998	OJ2000/C293/06	Pressure regulators for use with medical gases – Part 3: Pressure regulators integrated with cylinder valves.	BSEN 738-3: 1999
CEN EN 738-4: 1998	OJ2000/C293/06	Pressure regulators for use with medical gases – Part 4: Low pressure regulators intended for incorporation into medical equipment.	BSEN 738-4: 1999
CEN EN 980 Amendment 1	OJ2000/C293/07	Graphical symbols for use in the labelling of medical devices.	BSEN 980: 1997 (Amendment incorporated)
CEN EN 1089-3 Amendment 1	OJ2000/C293/06	Transportable Gas cylinders – Gas cylinder identification – Part 3: Colour coding.	EN 1089-3: 1997 (Amendment incorporated)
CEN EN1865: 1999	OJ2000/C293/06	Specifications for stretchers and other patient handling equipment used in road ambulances.	BSEN 1865: 2000
CEN ENISO 10079-1: 1999	OJ2000/C293/06	Medical suction equipment – Part 1: Electrically powered suction equipment – Safety requirements (ISO 10079-1: 1999)	BSENISO 10079-1: 2000
CEN ENSIO 10079-2: 1999	OJ2000/C293/06	Medical suction equipment – Part 2: Manually powered suction equipment (ISO 10079-2: 1999)	BSENISO 10079-2: 2000
CEN ENISO 10079-3: 1999	OJ2000/C293/06	Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source (ISO 10079-3: 1999)	BSENISO 10079-3: 2000
CEN ENISO 10535: 1998	OJ2000/C293/06	Hoists for the transfer of disabled persons – Requirements and test methods (ISO 10535: 1998)	BSENISO 10535: 1998
CEN ENISO 1055-1 Amendment 1	OJ2000/C293/06	Sterile, single-use intravascular catheters – Part 1: General requirements (ISO 10555-1:1996/Amd 1: 1999)	BSENISO 10555-1: 1997 (Amendment incorporated)
CEN ENISO 11990: 1999	OJ2000/C293/06	Optics and optical instruments – Lasers and laser-related equipment – Determination of laser resistance of tracheal tube shafts (ISO 11990: 1999)	
CEN EN 12006-1: 1999	OJ2000/C293/06	Non active surgical implants – Particular requirements for cardiac and vascular implants – Part 1: Heart valve substitutes.	BSEN 12006-1: 2000
CEN EN 12182: 1999	OJ2000/C293/06	Technical aids for disabled persons – General requirements and test methods.	BSEN 12182: 1999
CEN EN 12218: 1998	OJ2000/C293/06	Rail systems for supporting medical equipment.	BSEN 12218: 1999
CEN EN 12470-1: 2000	OJ2000/C293/06	Clinical thermometers – Part 1: Metallic liquid-in-glass thermometers with maximum device.	BSEN 12470-1: 2000
CEN EN 12470-3: 2000	OJ2000/C293/06	Clinical thermometers – Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device.	BSEN 12470-3: 2000
CEN EN 13220: 1998	OJ2000/C293/06	Flow-metering devices for connection to terminal units of medical gas pipeline systems.	BSEN 13220: 1999