

FDA, EUROPEAN AND CANADIAN CLASSIFICATION OF THE FLOTEC DEVICES

C L A S S I F I C A T I O N			
Code of Federal Regulation Food and Drugs 21 (April 2008) Flotec Devices	FDA 21 Classification (April 2010)	European Commission Meddev 2.4/1 Rev 9 PART 2 Rule 11- Active devices to administer, remove medicines and other substances to or from the body, or Directive 93/42/EEC- 14-Jun-93	Health Canada "Canada Medical Device Regulations" (SOR/98-282) Classification Rules for Medical devices; Part 1; Rule 9 (1) -an active therapeutic device, intended to be use to administer or withdraw energy to or from the body.
868.2350 Medical Gas FLOWMETER	CLASS 1 (general controls) Product Code - BXY 510(k) Exempt Sp.E, p.807, 868.9	CLASS 2B pressure regulator for medical gases	CLASS 2 Medical Gas Flowmeter
868.2350 Medical Gas Flow Control Valve, FCV w/4:1 Conserver	CLASS 1 (general controls) Product Code - BXY 510(k) Exempt Sp.E, p.807, 868.9	CLASS 2B pressure regulator for medical gases	CLASS 2 Medical Gas Flow Control Valve (FCV), FCV w/4:1 Conserver
868.2700 Medical Pressure Regulator	CLASS 1 (general controls) Product Code - CAN 510(k) Exempt Sp.E, p.807, 868.9	CLASS 2B pressure regulator for medical gases	CLASS 2 Medical Pressure Regulator
868.5905 Noncontinuous Ventilator (OXYSAVRR)	CLASS 2 (performance standards) Product Code - NFB 510(k) Required	CLASS 2B pressure regulator for medical gases	CLASS 2 Oxysavrr
868.2610 Medical gas PRESSURE GAUGE	CLASS 1 (General Controls) Product Code - BXH 510(k) Exempt Sp.E, p.807, 868.9	CLASS 2B pressure regulator for medical gases	CLASS 2 Medical gas Pressure gauge
868.5340 Nasal oxygen CANNULA	CLASS 1 (General Control) Product Code- CAT 510(k) Exempt Sp.E, p.807, 868.9	CLASS 2B pressure regulator for medical gases	CLASS 2 Nasal oxygen cannula
868.5860 Pressure tubing and accessories -Oxygen Manifold Assy -Mass Casualty, MCA and MCC	CLASS 1 (General Control) Product Code- BYX 510(k) Exempt Sp.E, p.807, 868.9	CLASS 2B pressure regulator for medical gases	CLASS 2 Oxygen Manifold Assemblies
880.6740 Vacuum-powered body fluid suction apparatus (VACUUM-REGULATOR) PENDING	CLASS 2 (Special Control) Product code - KDP 510(k) Exempt Sp.E, p.807, 880.9	CLASS 2A Suction equipment	CLASS 2 Vacuum Regulator
868.5925 - Powered emergency ventilator devise 868.5965 - Positive & expiratory pressure (PEEP) (CPAP Flow Generator) PENDING	CLASS 2 (performance standards) Product Code- BTL Product Code - BYE	CLASS 2B Powered emergency ventilator devise (CPAP FLOW GENERATOR)	Class 2 Powered emergency ventilator devise (CPAP FLOW GENERATOR)