FLOTEC
MADE IN USA

7625 West New York Street Indianapolis IN 46214-4911
Phone: 317-273-6960 Fax: 317-273-6979
e-mail: orderdesk@floteco2.com

www.floteco2.com
Order Desk: 800-401-1723

History

Flotec, incorporated in 1983, creates respiratory products that enable providers to saves lives. Since the beginning, the core activity has been manufacturing for the medical, industrial, and Original Equipment Manufacturing markets. The products include: specialized regulators, pressure reducers, flow control valves, liquid oxygen valves, fill to vent valves, quick disconnect fittings, relief valves, economizers, vent to fill valves for the medical market, and customized fluid power connectors, diesel fuel fittings, and other valves for the industrial market.

Products

In 1992, Flotec introduced the 'RW Series Regulator'. The 'RW Series Regulator' was designed to reduce the cost of ownership, while providing a complete range of features and options. The Flotec engineering and design team endeavored to create a product with the end user in mind. The goal was to produce a regulator that would be easy to read, easy to attach to the cylinder, easy to adjust, easy to identify, and at the same time, be reliable, accurate, durable, and above all, safe.

The RW series, the first generation of Flotec regulators, met many of the design team's goals. It also began a tradition and an expectation that the company would be the innovator in the oxygen regulator market.

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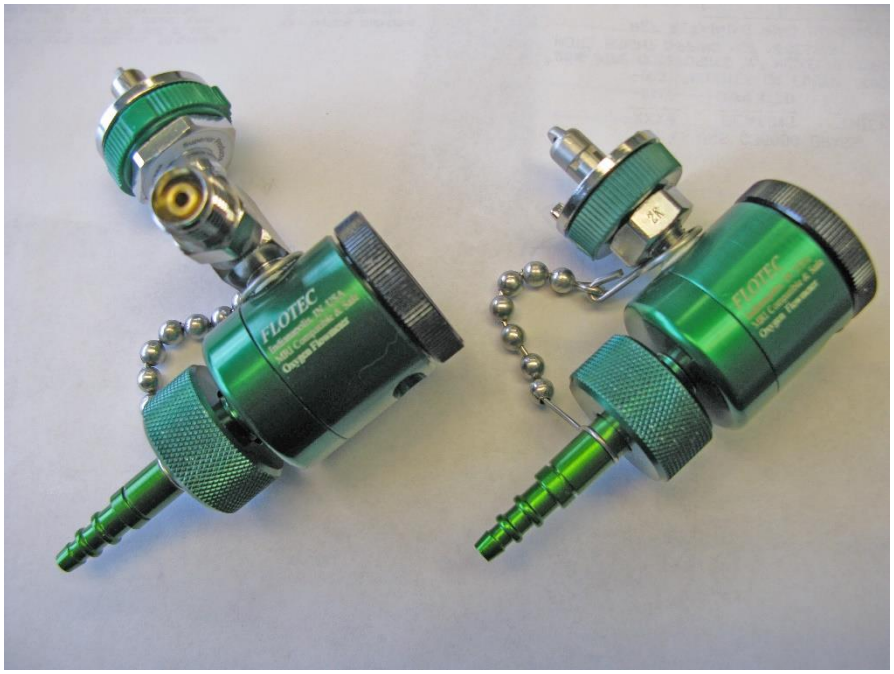
This regulator was the first to feature a low-profile contents gauge positioned to prevent breakage, the first to offer a large window through which to read the flow rates, the first to have high visibility night-glow numbers, and the first to feature a soft seat, finger tight post valve seal with a stay-put design. (This meant that the yoke seal washer would cling to the pin on the post valve and that the regulator could be attached to the post valve using minimal hand strength). Flotec was also the first to offer custom colors. Customers began ordering regulators in 12 distinct colors. No longer were regulators available in only silver or green. Since the flow-meter section could be ordered in a different color from the main body, Customers took advantage of this feature to further individualize their regulators. Flotec began the service of offering permanent and custom laser marking. No more paper decals. The Flotec RW regulator was first to feature an all-brass high-pressure inlet zone. Snap ring construction, common at the time, was eliminated, which was a new safety feature. Finally, the modular design enabled Flotec to easily customize the features of the regulator to the individual customer's demands. The Flotec customer can now choose from 4 trillion possible regulator combinations. In response to market demand, Flotec also began to manufacture regulators for other medical gases and various gas blends.

These innovations spurred demand for Flotec to create other related products incorporating these innovations. The product line increased to include Flowmeters.



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In 1999, Flotec introduced the InGage Series regulator. With this new product, Flotec perpetuated its mission to be the marketplace innovator. Although the low-profile contents gauge and its location on the RW regulator did lessen the possibility of damage, the problem still existed.

In response, Flotec created a regulator with a unique internal contents gauge which assures complete protection against all potential external impact damage. Like the RW series, this new content gauge features glow-in-the-dark, easy to read numbers. Thus, the InGage was born. The internal gauge was not the only new innovation to be included in this new series. The engineering team devised a unique method for double filtering the incoming gas. A special sintered depth filter was mounted on the inlet orifice.

Additionally, the rotor flow orifice was designed with a filter. This process ensures that the laser drilled flow orifices are kept free of debris. In order to provide the user with the freedom to position the outlets and the contents gauge to their own satisfaction, the swivel body was designed. This unique swivel body can be rotated a full 360 degrees. To further ease the process of attaching the regulator to the oxygen tank, a dynamic finger tight post-valve seal was created. This seal was permanently mounted on the regulator's inlet. This eliminated the need for reinstalling a washer on successive uses.

The new dome handle securing knob was introduced to eliminate the possibility of damage to the thread insert. Finally, because the basic appearance of the RW regulator had been copied by others, it was decided to change from a round shape to a dodecagon (12 sided) body.

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The third generation of the oxygen distribution manifold evolved incorporating the use of four, five or six hose assemblies between each flowmeter. The added space between each patient, or rehabbing Firefighter, provides for optimum care and less chaos during emergency situations. The 20-foot leader hose can be easily connected to the ambulance/or other gas source, while providing space for triage.

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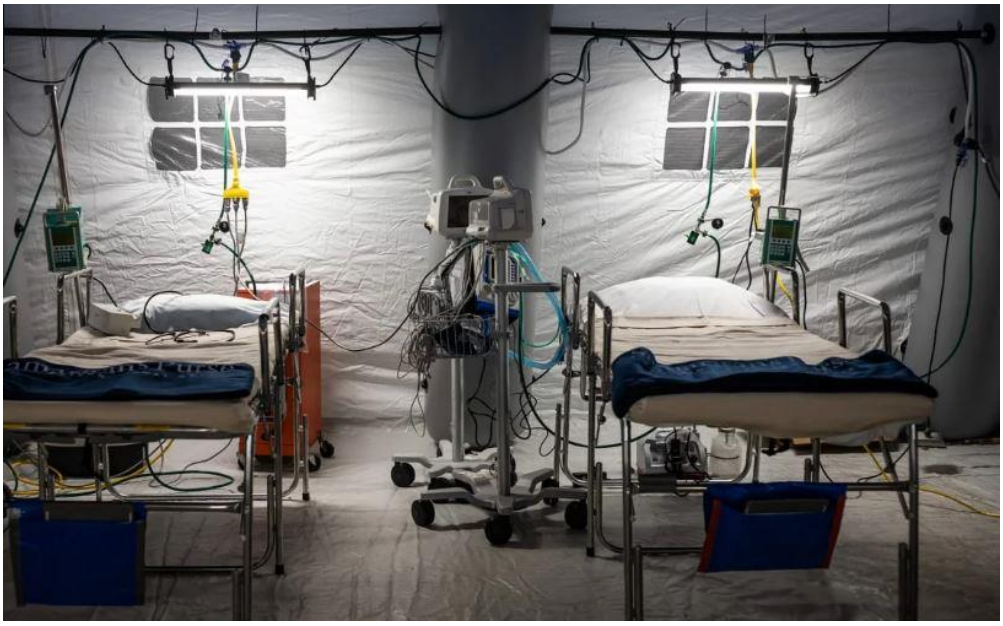
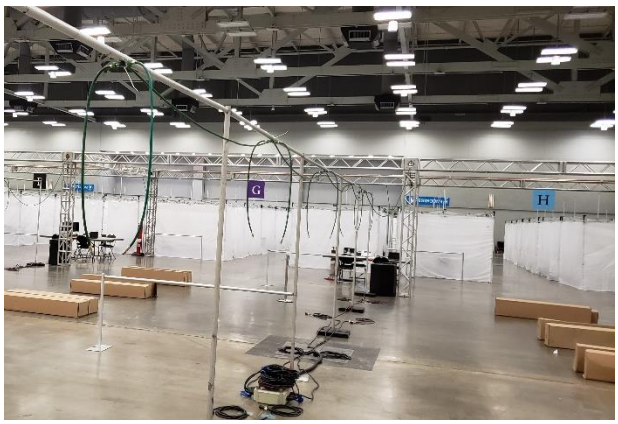
With the onset of Covid, the Flotec manifold system became an important solution for portable hospitals and mobile disaster response units. The addition of hose "drops" (extensions from the main distribution lines) situates flowmeters within close proximity to the patient and the caregiver. Demand for the manifolds in intensive care units and surgical centers increased. The latest innovation includes a vacuum system designed for portable surgical suites. Manifolds for Medical Air have recently been made available.



Here is a typical Convention Hall that was converted into a 460 room Mass Casualty Facility. Liquid Oxygen Trailers connected to heat exchangers outside the Convention Hall which converted the Liquid Oxygen into 11,500 liters per minute so that each room had 25 liters per minute to each flowmeter.



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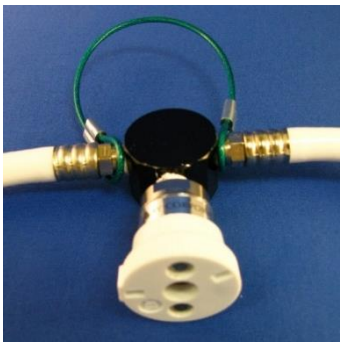
In order to meet demand from the international markets, Flotec has upgraded the hose used in the Mass Casualty Assemblies, so that Flotec Hose Assemblies are free of Di(2-ethylhexyl)phthalate (DEHP) and free of Volatile Organic Compounds (VOC). Based on design & testing, Flotec Hose Assemblies are free of Phthalates that may be **C**arcinogenic, **M**utagenic, or toxic to **R**eproduction

Flotec Hose Assemblies meet or are compliant with the following standards:

ISO 10993-1: 2009	Biological evaluation of medical devices
ISO 1307:2006	Rubber and plastics hoses — Hose sizes, minimum and maximum inside diameters, and tolerances on cut-to-length hoses.
ISO 13485: 2016	Medical Devices – Quality Management Systems
ISO 1402:2009	Rubber and plastics hoses and hose assemblies — Hydrostatic testing
EN ISO 14971:2012	Application of risk management to medical devices.
ISO 15001:2010	Anesthetic and respiratory equipment — Compatibility with oxygen
ISO 18562-3: 2017	Tests for emissions of volatile organic compounds (VOCs)
ISO 5359:2014	Low pressure hose assemblies for use with medical gases
ISO 8033:2016	Rubber and plastics hoses — Determination of adhesion between components
ISO 9170-1:2008	Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum
RoHS Directive	Restriction of Hazardous Substances Directive
CGA G-4.1-2018	Cleaning of equipment for oxygen service
SOR/98-282	Canadian Medical Device Regulations
CAN/CSA-Z5359:16	Low pressure hose assemblies for use with medical gases Exemption 4.6.11B; Hose is nonconductive.







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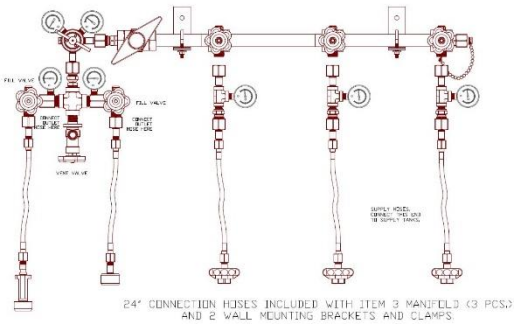
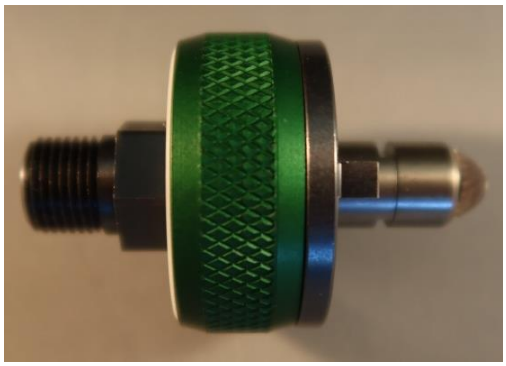
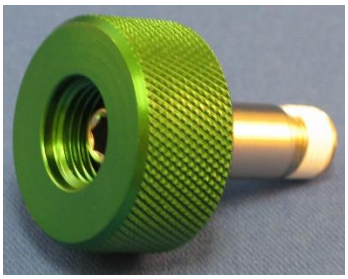
In order to enable Emergency Medical Services to become more independent from their gas suppliers, Flotec has developed a series of trans-filling systems. These systems enable, the EMS responders to trans-fill their own tanks economically, efficiently and most importantly, safely.



Flotec also manufactures a wide selection of accessory items.





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At Flotec, Inc., our team is constantly endeavoring to improve and broaden the Flotec product line, our quality systems, and manufacturing procedures. For more information, on these existing products and future products, please contact us by phone (317) 273-6960 or tool free (800) 401-1723, or by email at info@floteco2.com.

Because, we can!

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Facility

In May of 1998, Flotec relocated to a state-of-the-art manufacturing location at 7625 West New York Street in Indianapolis. This new space enabled Flotec to expand and improve the research and development department as well as the assembly operation.

Regulator Assembly

Liquid Oxygen Flow Control Valve Testing

Regulator Assembly

Liquid Oxygen Flow Control Valve Assembly

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Liquid Oxygen Flow Control Valve Assembly

Liquid Oxygen Flow Control Valve Testing

Personal Demand Device Valve Testing

Inspection

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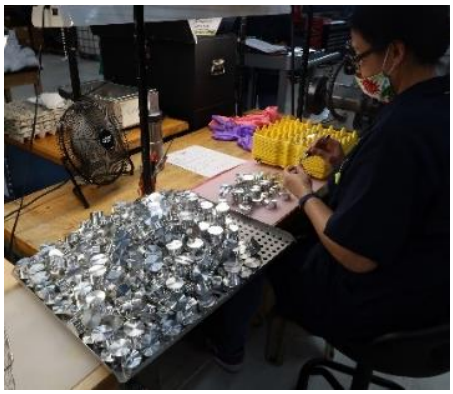

Deburr

Deburr

Ultrasonic Cleaning

Secondary Operations

Secondary Operations

Lasers, 50 & 30 Watt Fiber & 50 Watt CO2

Laser, 50 Watt Fiber

Laser, 50 Watt Fiber

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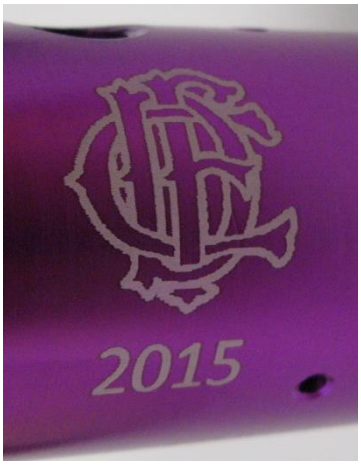
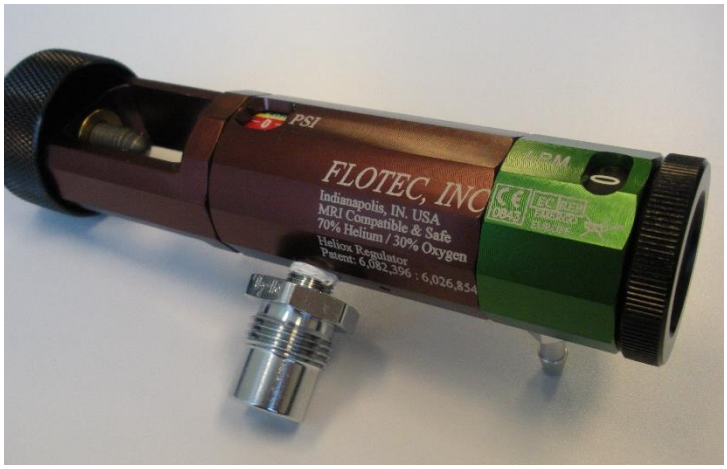
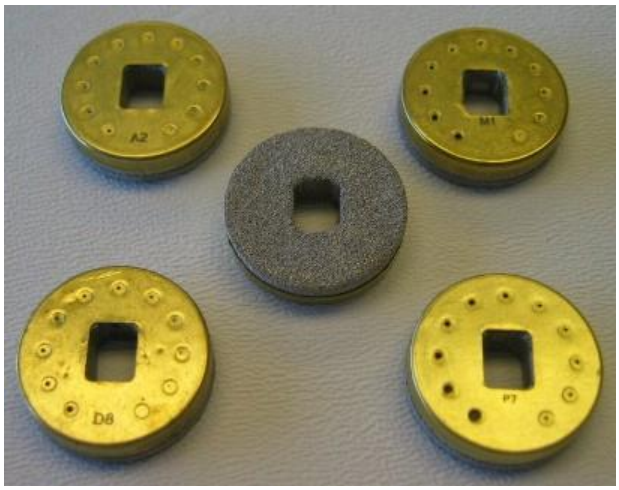
Laser, 50 Watt Fiber

Laser, 50 Watt Fiber







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Star SR38 type B (10 Axis Swiss Lathe)

Star SR32J (7 Axis Swiss Lathe)

Miyano ABX-64DHY2 (7 Axis Lathe)

Miyano ABX-64SY (8 Axis Lathe)

Miyano ABX-51TH2 (10 Axis Lathe)

Star SK-51 (8 Axis Lathe)

Star SR38 type B (10 Axis Swiss Lathe)

Star SR32J (7 Axis Swiss Lathe)

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Regulatory

Flotec's quality system was audited on December 16, 2003, was found compliant with all the requirements, and was issued ISO 9000:2000 and ISO 13485:1996. Flotec continued to maintain this certification and work toward further improvements. In April of 2005, Flotec was issued ISO 13485:2003 and in September of 2009, Flotec was issued ISO 9001:2008. In August of 2014 Flotec earned ISO 9000:2008, ISO 13485:2003 / Cor 1:2009, and ISO 13485-03 (R2008). In October 2018 Flotec was issued ISO13485:2016 and MDSAP.

FDA - United States 21 CFR 820, 803, 806, 807 (subparts A & D), & 821 (where applicable)

FDA 21 CFR Part 820, also known as the Quality System Regulation (QSR), is a document that outlines Current Good Manufacturing Practice (CGMP) regulations. This document governs manufactures to help ensure their products consistently meet applicable requirements and specifications. FDA 21 CFR Part 820 is the quality system approved by the FDA. These requirements are to ensure that medical devices are both safe and effective. Medical device manufacturers undergo FDA inspections to ensure FDA 21 CFR 820 compliance.

ISO13485:2016

ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support).

MDSAP – Medical Device Single Audit Program: Australia: Therapeutic Goods Regulations; Canada: Medical Device Regulations (SOR 98/282); United States: 21 CFR 820, 803, 806, 807 (subparts A & D), & 821 (where applicable)

The Medical Device Single Audit Program – or MDSAP – allows a single regulatory audit of a medical device manufacturer's quality management system to satisfy the requirements of multiple regulatory authorities (RAs). Five RAs: Australian Therapeutic Goods Administration (TGA), Brazil's Agência Nacional de Vigilância Sanitária (ANVISA), Health Canada, MHLW/PMDA (Japan), and the US Food and Drug Administration (FDA) participated in a three-year MDSAP Pilot which concluded in December 2016. These RAs will continue to participate in MDSAP as the program moves into its operational phase starting January 2017, with Health Canada making a full transition from the Canadian Medical Devices Conformity Assessment System (CMDCAS) to MDSAP. (Note: Manufacturers selling into Canada will have until January 1, 2019 to be certified to MDSAP.)

CE Mark

CE marking is an administrative marking that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA). (It is not a quality indicator or a certification mark.) The CE marking is also found on products sold outside the EEA that have been manufactured to EEA standards. This makes the CE marking recognizable worldwide even to people who are not familiar with the European Economic Area. It is in that sense like the FCC Declaration of Conformity used for selling certain electronic devices in the United States. The CE marking is the manufacturer's declaration that the product meets EU standards for health, safety, and environmental protection.

MDD - Medical Device Directive (Expired) (MDR – Medical Device Regulation PENDING)

The **Medical Device Directive** (Council Directive 93/42/EEC of 14 June 1993 [1] concerning medical devices, OJ No L 169/1 of 1993-07-12) is intended to harmonize the laws relating to medical devices within the European Union. The MD Directive is a 'New Approach' Directive and consequently in order for a manufacturer to legally place a medical device on the European market the requirements of the MD Directive have to be met. Manufacturers' products meeting 'harmonized standards' have a presumption of conformity to the Directive. Products conforming with the MD Directive must have a CE mark applied. The Directive was most recently reviewed and amended by the 2007/47/EC and a number of changes were made. Compliance with the revised directive became mandatory on 21 March 2010. The Medical Devices Directive is being repealed and replaced by the 2017 EU Medical Device Regulation (EU 2017/745), effective on 26 May 2021.[3]

UDI – Unique Devise Identification

The **Unique Device Identification** (UDI) System is intended to assign a unique identifier to medical devices within the United States, Europe, China, South Korea, Saudi Arabia and Taiwan[1]. It was signed into law in the US on September 27, 2007, as part of the Food and Drug Administration Amendments Act of 2007. The EU acted to adopt UDI and on April 5, 2017, under the EU Medical Device Regulation (MDR) and In-vitro Diagnostic Regulation (IVDR), but adoption has been postponed to 2021.

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Medical Device	Jurisdictions	Class	Justification for Class	Route to Market Approval
RW Regulator	US	Class I	21 CFR 868.2700	510(k) exempt
	Canada	Class II	Rule 9 of CMDR	SOR-98-282 Part 1
	EU	Class IIb	Rule 11 of MDD MEDDEV 2.4/1 rev 9	Annex II of MDD
	Australia	Class IIb	Rule 4.4(2) of TG(MD)R	TG(MD)R Sch3 P1
	Israel	Same as US	Article 10 of MER	MER 3
InGage Regulator	US	Class I	21 CFR 868.2700	510(k) exempt
	Canada	Class II	Rule 9 of CMDR	SOR-98-282 Part 1
	EU	Class IIb	Rule 11 of MDD MEDDEV 2.4/1 rev 9	Annex II of MDD
	Australia	Class IIb	Rule 4.4(2) of TG(MD)R	TG(MD)R Sch3 P1
	Israel	Same as US	Article 10 of MER	MER 3
Flowmeter	US	Class I	21 CFR 868.2350	510(k) exempt
	Canada	Class II	Rule 9 of CMDR	SOR-98-282 Part 1
	EU	Class IIb	Rule 11 of MDD MEDDEV 2.4/1 rev 9	Annex II of MDD
Mass Casualty Assembly	US	Class I	21 CFR 868.5860	510(k) exempt
	Canada	Class II	Rule 9 of CMDR	SOR-98-282 32(2)
	EU	Class IIb	Rule 11 of MDD MEDDEV 2.4/1 rev 9	Annex II of MDD
Hose Assembly	US	Class I	21 CFR 868.5860	510(k) exempt
Hose Assembly – Canadian Standard	Canada	Class II	Rule 5 of CMDR	SOR-98-282 32(2)