




Declaration of Conformity – Hose Assembly - Canadian Standard

Product Identification & Classification

Product	Part Number	Canada Class
Canadian Hose Assembly	HCW8-4S8S-XXX HCW8-3C8S-XXX	Class II, by rule 5 of SOR-98-282.

Manufacturer

Name of company	Address	Contact information
Flotec, Inc. 	7625 West New York Street Indianapolis, Indiana 46214-4911 United States of America	+1 317-273-6960 - telephone +1 317-273-6979 - fax Orderdesk@floteco2.com

Standards applied

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.

As of the date specified, this documents the compliance status of Flotec Canadian Hose Assemblies.
For an up-to-date listing of standard compliance contact QA@Floteco2.com

Brian R. Davidson

Title: President

Date: 2020-09-30