CLEARFLOW
ACTIVE CLEARANCE TECHNOLOGY

Declaration of Conformity

Manufacturer: Address:	ClearFlow, Inc. 1630 S. Sunkist St., Suite E Anaheim, CA 92806 USA
European Representative: Address:	Emergo Group Prinsessegracht 20 2514 AP The Hague The Netherlands
Notified Body:	National Standards Authority of Ireland 1 Swift Square Northwood, Santry Dublin 9, Ireland
NB Identification #	0050
Conformity Assessment:	Annex II, Section 3.2 of the Directive 93/42/EEC on Medical Devices, as amended by 2007/47/EEC
EC Certificate Number:	252.1078
ISO Certificate Number:	MD 19.4770
Device Classification:	IIa
Rule per Annex IX:	7
Product Family:	Thoracic Drain (Product listing is attached)

List of Applied Harmonized Standards:

EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for regulatory purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN 1618:1997	Catheters other than Intravascular Catheters. Test Methods for Common Properties
ISO 15223-1:2016	Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be Supplied – Part 1: General Requirements
EN 1041:2008	Information Supplied by the Manufacturer of Medical Devices
ISO 10993-1:2009	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management System
ISO 10993-7:2008	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals

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ISO 11135-1:2007	Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices
ISO 11607-1:2009	Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems.

We herewith declare that the above mentioned product(s) meet the provisions of the EC Council Directive 93/42/EEC concerning medical devices (MDD93/42/EEC) which apply to them and stated in Annex II of this directive, as amended by 2007/47/EC.

Date: March 27 2018

Signature: Dov Gal

Name: Dov Gal

Title: Vice President Regulatory and Clinical Affairs and Quality Assurance

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ClearFlows' Product Listing

Reference Number	Product Description	UMDN Code	Date 1st CE Marked
PF-20	PleuraFlow System 20Fr	11308	10 June 2010
PF-24	PleuraFlow System 24Fr	11308	10 June 2010
PF-28	PleuraFlow System 28Fr	11308	10 June 2010
PF-32	PleuraFlow System 32Fr	11308	10 June 2010
PF-20 SEDL	PleuraFlow System 20Fr with Short Effective Drainage Length (SEDL)	11308	01 June 2016
PFFG-20	PleuraFlow System with FlowGlide™ 20Fr	11350, 37482, 32544	22 August 2017
PFFG-24	PleuraFlow System with FlowGlide™ 24Fr	11350, 37482, 32544	22 August 2017
PFFG-28	PleuraFlow System with FlowGlide™ 28Fr	11350, 37482, 32544	22 August 2017
PFFG-32	PleuraFlow System with FlowGlide™ 32Fr	11350, 37482, 32544	22 August 2017

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Declaration of Conformity Change History

Date	Rev.	Description of Change	Reason for Change
08/23/2013	A	Initial Release for CCS, previous revisions held by Xeridiem.	n/a
08/29/2013	B	Updated the ISO Certificate #.	MD # needed
02/12/2014	C	Change of company name and address.	HQ Relocation
06/09/2015	D	Removal of individually-packaged chest tubes.	Discontinue distribution of individually-packaged chest tubes and removal from distribution
2/15/2016	E	Correcting the erroneous address from Irvine to Anaheim.	Correct address
5/1/2016	F	Adding a PleuraFlow System model PF-20 SEDL to the product family.	Adding a new model
8/22/2017	G	1. Updating the address of the European Authorized Representative 2. Updating the GMDN numbers due to an existing GMDN being obsoleted. New GMDN numbers are 11350, 32544 and 37482, which are reflected on the revised certificate. Design updates / changes: 3. The terminal end of the core wire is now laser welded rather than twisted 4. The welded segment of the core wire is covered with a PTFE heat shrink sleeve 5. Added FlowGlide™ coating to the internal and external surfaces to reduce friction and to allow easier sliding of the Clearance Wire assembly 6. Modification to chest tube printing to add the word FlowGlide™ for models with the coating 7. The sterile barrier pouch was modified by adding a bumper seal separating the pouch into two areas, one for the chest tube and one for the Clearance Apparatus 8. Modification to backer card that holds clearance apparatus in pouch	Broadening the product family
3/27/18	H	Update ISO 13485:2012 to EN ISO 13485:2016; Update EN ISO15223-1:2012 to EN ISO15223-1:2016; Update the Signature Title; update the company's name in the header of product listing and correct a typo in product description last line	Update QMS with new ISO revisions. Change the signature responsibility to head of RA/QA