

Declaration of Conformity

Product Identification	
Product group name	Model Numbers
Infection Control Filters	ICF-SDSS; ICF-SDRC

Manufacturer		
Name of Company	Address	Representative
X-Flow BV (a subsidiary of Pentair Inc.)	Marssteden 50, 7547 TC Enschede The Netherlands	Mr. Frank van Heusden

Registration Information		
Independent regulatory affairs consultant	CE Certificate Number	Date CE Marking first applied
CEpartner4U BV	Not applicable	2015-10-01

Device Classification	Route to Compliance
Class I	MDD 93/42/EEC, Annex VII As amended: 2007/47/EC

X-Flow BV declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices. All supporting documentation is retained at the premises of the manufacturer.

This Declaration of Conformity covers the Infection Control Filters as specified in the product list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site(s):

MANUFACTURING SITE: Marssteden 50, 7547 TC Enschede, NL

COMPANY REPRESENTATIVE: Frank van Heusden

TITLE: Senior Product Manager

DATE: 01/10/2015

Appendix

Date: 01-10-2015**Product list****Medical Water Filters**

This product list belongs to the Declaration of Conformity identified by DoC Filtrix MWF Class I 09-12-EN and specifies the CE marked products concerned that Filtrix BV intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Device Name	Type/Model/Ref	Risk Class / rule	Date of first Batch/Lot
ICF ShowerFilter Deluxe Start-set	ICF-SDSS 322200	Class I / rule 1	2015-10-01
ICF ShowerFilter Deluxe Replacement Cartridge	ICF-SDRC 322100	Class I / rule 1	2015-10-01
ICF Cartridge	ICF-RC 321500	Class I / rule 1	2015-10-01