



Certificate of Conformance

Manufacturer:

Equflow B.V.
Postbus 35
5370 AA Ravenstein
Langakker 5F
NL-5371 EV Ravenstein

Distributor:

High Purity New England
25 Thurber Boulevard
Unit # 4
Smithfield, RI 02917

Description	PVDF
Part Number	
Lot Number	
Date of Manufacture	June 11, 2013
Expiration Date	June 11, 2016

The flow tubes manufactured are in compliance with the manufacturer production and quality directives. The products are submitted by the manufacturer to the factory production control department that has performed the initial outgoing inspection.

The materials used in construction of the flow tubes are in compliance with the requirements of USP Class VI. PVDF Solef® 1008 has been tested according to USP chapter 88 "Biological reactivity tests, in vivo" and has demonstrated its compliance with the requirements of USP Plastic Class VI. Although USP Class VI testing is widely used and accepted in the medical products industry, it does not fully meet any category of ISO 10993-1 testing guidelines for medical device approval. Each specific type of medical product must be submitted to appropriate regulatory authorities for approval. Solvay Solexis does not allow nor support the use of any of our products in any permanent implant applications. PVDF Solef® 1008 supplied in the original sealed packaging does not come into contact with any substance of animal origin, during all the operations made under the control of Solvay Solexis.

Based on the above, we are confident that the above-cited products are not contaminated by infective agents responsible for transmitting BSE/TSE.

This certificate attests that all provisions concerning the attestation of production control were applied.