



Declaration of US Pharmacopeia Class VI

Manufacturer:

Equflow bv
PO BOX 6671
NL-6503 GD Nijmegen
Netherlands

Declares that:

Description	PVDF Turbine Flowtubes, made of PVDF Solef 1008/0001
Article P/N	0045.P.H.0.00.TX 0045.P.H.0.00.CX 0085.P.H.0.00.TX 0085.P.H.0.00.CX
Prod. number	N.A.
Date of manufact.	N.A.
Expire	N.A.
Serial number	N.A.

Are in compliance with the requirements of USP Class VI.

based on the statement of the supplier:

Medical applications

Solef® PVDF 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. For any questions regarding our implant policy, please contact your Solvay Solexis representative.

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