

TECHNICAL PRODUCT FORM *In-Flow*

Trade Name of the Device: *In-Flow*

Generic description: Intraurethral bladder drainage device for women with atonic bladder.

Catalogue Numbers listed: 203511-30, 203511-35, 203511-40, 203511-45, 203511-50, 203511-55, 203511-60, 203511-65, 203511-70

Product Components:

1. Shaft
2. Rotor
3. Magnet
4. Screw
5. Stator in
6. Stator – out
7. Nut
8. Plug
9. Tube
10. Catheter
11. Extender
12. Graber
13. Pusher

Material of Components:

Stainless Steel ASTM f-138/92
 Polycarbonate- Lexan HF-1140, R-112
 Neodymium iron boron magnet Nd2Fe14B
 Stainless Steel ASTM f-138/92
 Polycarbonat - Lexan HF-1140,R112
 Polycarbonat - Lexan HF-1140,R112
 Stainless Steel ASTM f-138/92
 Silicon LR-3003/50
 Polycarbonat - Lexan HF-1140,R112
 Silicon LR-3003/70
 Silicon LR-3003/70
 Nylon 6.6
 Nylon 6.6

Manufacturer:

Vesiflo Inc,

Address:

8672 154TH Ave NE Redmond WA 98052 USA

Liability Insurance:

MEDMARC Casualty Insurance Company, 14280 Park Meadow Drive, Suite 300, Chantilly, VA 20151-2219

Sterilisation Method / Time: Radiation / 3 Years steril

Sterilisation Address:

1265-B Kennestone Circle, Marietta, GA 30066 U.S.A.

Sterilisation Controls:

ISO 11137, AAMI TIR 27

CE – Mark number:

0459

Notified body:

BVQI (Gmed)

Product classification:

II a

Packaging Type:

Blister und Pouch,

& Material:

PETG 0.7(Tray), TYVEK, HDPE (Pouch), Duflex (Box)

Simple or double:

Double

Number of units

per sterile packaging:

1

Authorized European

Representative:

mtm | medical | technology | marketing

Waffenschmiedweg 30 A, 86911 Diessen, Germany

Tel.: +49. (0) 8807.91138 Fax: +49.(0)8807.940899

E-Mail: mw@mtm-med.com