EC DECLARATION OF CONFORMITY

Name	Device Description	Basic UDI-DI
Ergofilter® SP1 (FF1028) Ergofilter® SP1M (FF1029)	Antibacterial and single use filter to ensure a good fit with the SPL10-USB and optimal protection against bacteriological risks	**376025345FF1028TK**

The device conforms to the following standards:

NF EN ISO 13485 :2016 : Medical Device – Quality Management System
NF ISO 2859-1 :2000 : Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
EN 62366-1:2015: Medical devices - Application of usability engineering to medical devices
EN ISO 10993-1:2009/AC: 2010: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
EN ISO 10993-5:2009 : Biological evaluation of medical devices - Part 5 : In vitro cytotoxicity test
EN ISO 10993-10:2010 : Biological evaluation of medical devices - Part 10 : Test for irritation and skin sensitization
NF EN ISO 14971:2019 : Medical devices - Application of risk management to medical devices
NF EN 1041+A1:2013: Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General

I the undersigned, Dounia Benbachir, Quality Manager of the FIM MEDICAL company located at 51 rue Antoine Primat Villeurbanne - FRANCE assure and declare that the medical devices listed above belong to class IIa (Rule 5) and satisfy the provisions of annex I (Essential Requirements), annex VI (Product Quality Assurance) and annex VII (Evaluation of Ergofilter® SPL1 et SP1M, FF1028DTR100 technical file) of the 93/42/EEC directive and its local adaptation (Book V of the public health code).

The devices described above are covered by the EC Certificate n° 27671 delivered by LNE/G-MED, 1 rue Gaston Boissier, 75724 Paris Cedex 15.

Villeurbanne, 13/07/2021,
D.BENBACHIR

Responsable Qualité

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