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/A11:2021 : Medical devices – Quality Management System
EN ISO 10993-1:2020: 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 - Partie 5 : Tests for in vitro cytotoxicity
ISO 10993-10:2021: Biological evaluation of medical devices - Partie 10 : Tests for irritation and skin sensitization
NF EN ISO 14971:2019: Medical devices - Application of risk management to medical devices
ISO 20417:2021: Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2021: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General
NF ISO 2859-1 :2011 : Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

I the undersigned, Aliénor Boura, QARA Manager of the FIM MEDICAL SAS 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° 27671-9 delivered by GMED, 1 rue Gaston Boissier, 75724 Paris Cedex 15.

Villeurbanne, 04/04/2024,
A.Boura

Responsable QARA

CE
0459

EC Declaration of Conformity

Name	Device Description
Spirolyser® Q13 (FF1037)	Spirometer

Medical devices conform to the following standards:

NF EN ISO 13485:2016/A11:2021 : Medical devices – Quality Management System
IEC 60601-1:2005+AMD1:2012+AMD2:2020: Medical electrical equipment – Part 1: General requirements for basic safety
EN 60601-1-2:2015/Amd1:2020: Medical electrical equipment - Part 1-2: General requirements for basic safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6:2007/AC: 2010: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366-1:2015/Amd 1:2020: Medical devices - Application of usability engineering to medical devices
EN ISO 10993-1:2020: 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 - Partie 5 : Tests for in vitro cytotoxicity
ISO 10993-10:2021: Biological evaluation of medical devices - Partie 10 : Tests for irritation and skin sensitization
NF EN ISO 14971:2019: Medical devices - Application of risk management to medical devices
NF EN 62304/A1:2018: Medical device software -- Software life cycle processes
ISO 20417:2021: Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2021: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General
NF ISO 2859-1 :2011: Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
2005 American Thoracic Society/European Respiratory Society (ATS/ERS) recommendations on Standardization of Spirometry.

I the undersigned, Aliénor Boura, QARA Manager of the FIM MEDICAL SAS company located at 51 rue Antoine Primat Villeurbanne - FRANCE assure and declare that the medical devices listed above belong to class IIa (Rule 10) and satisfy the provisions of annex I (Essential Requirements), annex VI (Product Quality Assurance) and annex VII (Evaluation of Spirolyser® Q13 FF1037DTR100 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° 27671-9 delivered by GMED, 1 rue Gaston Boissier, 75724 Paris Cedex 15.

Villeurbanne, 04/04/2024,
A.Boura

Responsable QARA

CE
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EC Declaration of Conformity

Name	Matter	Device Description
Qflow® (FS1028)	Polypropylene	Single-use sensor

Medical devices conform to the following standards:

NF EN ISO 13485:2016/A11:2021 : Medical devices – Quality Management System
EN ISO 10993-1:2020: 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 - Partie 5 : Tests for in vitro cytotoxicity
ISO 10993-10:2021: Biological evaluation of medical devices - Partie 10 : Tests for irritation and skin sensitization
NF EN ISO 14971:2019: Medical devices - Application of risk management to medical devices
ISO 20417:2021: Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2021: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General
NF ISO 2859-1 :2011 : Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

I the undersigned, Aliénor Boura, QARA Manager of the FIM MEDICAL SAS 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 Spirolyser® Q13 FF1037DTR100 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° 27671-9 delivered by GMED, 1 rue Gaston Boissier, 75724 Paris Cedex 15.

Villeurbanne, 04/04/2024,
A.Boura

Responsable QARA

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