

Déclaration de conformité UE EU Declaration of conformity

Fabricant / *Manufacturer* : **AQUATOOLS SAS**

Siège social / *headquarters* : **11 rue Lobineau - 75006 Paris – France**

Etablissement principal / *main site* : **18, rue du Maréchal Foch – 80130 Friville - France**

Single registration number (SRN): not yet applicable

Déclarons sous notre seule responsabilité, que les dispositifs médicaux :

Declare under our sole responsibility, that the medical devices:

Filtre à usage unique, non-sterile, pour la distribution d'eau bactériologiquement maîtrisée, visant la protection des patients immunodéprimés.

Disposable water filter, non-sterile, for the distribution of bacteriologically controlled water, for the protection of immunocompromised patients.

Product name	Article number	Basic UDI-DI	Code GTIN
Filt'Ray 1M non-sterile tap filter, shower flow	AT30150	376027973FILTRAY2.5GNS87	03760279731483
Filt'Ray 1M non-sterile tap filter, straight flow	AT30151	376027973FILTRAY2.5GNS87	03760279731506
Filt'Ray 1M non-sterile screw-in shower filter	AT30161	376027973FILTRAY2.5GNS87	03760279731544
Filt'Ray 2M non-sterile tap filter, shower flow	AT30250	376027973FILTRAY2.5GNS87	03760279731407
Filt'Ray 2M non-sterile tap filter, straight flow	AT30251	376027973FILTRAY2.5GNS87	03760279731421
Filt'Ray 2M non-sterile screw-in shower filter	AT30261	376027973FILTRAY2.5GNS87	03760279731469
Filt'Ray 3M non-sterile tap filter, shower flow	AT30350	376027973FILTRAY2.5GNS87	03760279732145
Filt'Ray 3M non-sterile tap filter, straight flow	AT30351	376027973FILTRAY2.5GNS87	03760279732138
Filt'Ray 3M non-sterile screw-in shower filter	AT30361	376027973FILTRAY2.5GNS87	03760279732121
Filt'Ray 4M non-sterile tap filter, shower filter	AT30450	376027973FILTRAY2.5GNS87	03760279732084
Filt'Ray 4M non-sterile tap filter, straight flow	AT30451	376027973FILTRAY2.5GNS87	03760279732077
Filt'Ray 4M non-sterile screw-in shower filter	AT30461	376027973FILTRAY2.5GNS87	03760279732022

Sont des dispositifs médicaux de classe I conformes au **Règlement (UE) 2017/745**.

*Are Class I medical devices, complying with **Regulation (EU) 2017/745**.*

La classe de risque a été établie conformément aux règles de l'**Annexe VIII (Règle 1)**.

*The risk class has been established in accordance with the rules of **Appendix VIII (rule 1)**.*

La conformité à toutes les exigences réglementaires applicables aux dispositifs médicaux est maintenue par un **système de gestion de la qualité certifié ISO 13485** et est basée sur le **dossier technique n° DTFILTRAY2.5GNS**.

*Compliance with all applicable regulatory requirements for the medical devices is maintained by an **ISO 13485 certified quality management system** and is based on **technical documentation n° DTFILTRAY2.5GNS**.*

Friville, le 04/01/2023

Patrick Delabie

Directeur Général – General manager

