

Déclaration de conformité UE EU Declaration of conformity

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

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

Etablissement principal / *main establishment* : **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 ^{2G} Disposable Shower Head Water – 1 Month	AT030723	376027973FILTRAY2GNSEL	3760279730028
FILT'RAY ^{2G} Disposable Shower Head Water – 2 Months	AT030715	376027973FILTRAY2GNSEL	3760279730035
FILT'RAY ^{2G} Disposable Shower Head Water – 3 Months	AT030724	376027973FILTRAY2GNSEL	3760279730042
FILT'RAY ^{2G} Disposable Shower Head Water – 4 Months	AT030725	376027973FILTRAY2GNSEL	3760279730059
FILT'RAY ^{2G} Disposable Faucet Water Filter with straight flow outlet - 1 Month	AT030727	376027973FILTRAY2GNSEL	3760279730165
FILT'RAY ^{2G} Disposable Faucet Water Filter with straight flow outlet – 2 Months	AT030721	376027973FILTRAY2GNSEL	3760279730172
FILT'RAY ^{2G} Disposable Faucet Water Filter with straight flow outlet – 3 Months	AT030729	376027973FILTRAY2GNSEL	3760279730189
FILT'RAY ^{2G} Disposable Faucet Water Filter with straight flow outlet – 4 Months	AT030730	376027973FILTRAY2GNSEL	3760279730189
FILT'RAY ^{2G} Disposable Faucet Water Filter with shower flow outlet – 1 Month	AT030728	376027973FILTRAY2GNSEL	3760279730127
FILT'RAY ^{2G} Disposable Faucet Water Filter with shower flow outlet – 2 Months	AT030722	376027973FILTRAY2GNSEL	3760279730134
FILT'RAY ^{2G} Disposable Faucet Water Filter with shower flow outlet – 3 Months	AT030739	376027973FILTRAY2GNSEL	3760279730141
FILT'RAY ^{2G} Disposable Faucet Water Filter with shower flow outlet – 4 Months	AT030740	376027973FILTRAY2GNSEL	3760279730158
FILT'RAY ^{2G} Disposable Wall-mounted Shower Water Filter – 1 Month	AT030767	376027973FILTRAY2GNSEL	3760279730240
FILT'RAY ^{2G} Disposable Wall-mounted Shower Water Filter – 2 Months	AT030768	376027973FILTRAY2GNSEL	3760279730257
FILT'RAY ^{2G} Disposable Wall-mounted Shower Water Filter – 3 Months	AT030741	376027973FILTRAY2GNSEL	3760279730264
FILT'RAY ^{2G} Disposable Wall-mounted Shower Water Filter – 4 Months	AT030742	376027973FILTRAY2GNSEL	3760279730271
FILT'RAY ^{2G} Disposable Inline Water Filter – 3 Months	AT030743	376027973FILTRAY2GNSEL	3760279730226
FILT'RAY ^{2G} Disposable Inline Water Filter - 4 Months	AT030744	376027973FILTRAY2GNSEL	3760279730233

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° DTFILTRAY2GNS**.

*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° DTFILTRAY2GNS**.*

Friville, le 14/11/2022

Patrick Delabie

Directeur Général – General manager

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