

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-Escarbotin - France

Single registration number (SRN): FR-MF-000028808

Déclarons sous notre seule responsabilité, que les dispositifs médicaux :

Declare under our sole responsibility, that the medical devices:

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

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

Gamme Filt'Ray 2G / *Filt'Ray 2G Range*

Product name	Article number	Basic UDI-DI	Code GTIN
FILT'RAY ^{2G} Disposable Shower Head Water – 1 Month	AT030711	376027973FILTRAY2GSJJ	3760279730004
FILT'RAY ^{2G} Disposable Shower Head Water – 2 Months	AT030713	376027973FILTRAY2GSJJ	3760279730011
FILT'RAY ^{2G} Disposable Shower Head Water – 3 Months	AT030714	376027973FILTRAY2GSJJ	3760279731193
FILT'RAY ^{2G} Disposable Shower Head Water – 4 Months	AT030716	376027973FILTRAY2GSJJ	3760279731186
FILT'RAY ^{2G} Disposable Faucet Water Filter with straight flow outlet – 14 Days	AT030732	376027973FILTRAY2GSJJ	3760279730097
FILT'RAY ^{2G} Disposable Faucet Water Filter with straight flow outlet – 1 Month	AT030717	376027973FILTRAY2GSJJ	3760279730103
FILT'RAY ^{2G} Disposable Faucet Water Filter with straight flow outlet – 2 Months	AT030719	376027973FILTRAY2GSJJ	3760279730110
FILT'RAY ^{2G} Disposable Faucet Water Filter with straight flow outlet – 3 Months	AT030747	376027973FILTRAY2GSJJ	3760279731131
FILT'RAY ^{2G} Disposable Faucet Water Filter with straight flow outlet – 4 Months	AT030749	376027973FILTRAY2GSJJ	3760279731124
FILT'RAY ^{2G} Disposable Faucet Water Filter with shower flow outlet - 14 Days	AT030731	376027973FILTRAY2GSJJ	3760279730066
FILT'RAY ^{2G} Disposable Faucet Water Filter with shower flow outlet – 1 Month	AT030718	376027973FILTRAY2GSJJ	3760279730073
FILT'RAY ^{2G} Disposable Faucet Water Filter with shower flow outlet - 2 Months	AT030720	376027973FILTRAY2GSJJ	3760279730080
FILT'RAY ^{2G} Disposable Faucet Water Filter with shower flow outlet – 3 Months	AT030748	376027973FILTRAY2GSJJ	3760279731117
FILT'RAY ^{2G} Disposable Faucet Water Filter with shower flow outlet – 4 Months	AT030750	376027973FILTRAY2GSJJ	3760279731100
FILT'RAY ^{2G} Disposable Wall-mounted Shower Water Filter – 1 Month	AT030777	376027973FILTRAY2GSJJ	3760279731179
FILT'RAY ^{2G} Disposable Wall-mounted Shower Water Filter – 2 Months	AT030778	376027973FILTRAY2GSJJ	3760279731162
FILT'RAY ^{2G} Disposable Wall-mounted Shower Water Filter – 3 Months	AT030779	376027973FILTRAY2GSJJ	3760279731155
FILT'RAY ^{2G} Disposable Wall-mounted Shower Water Filter – 4 Months	AT030780	376027973FILTRAY2GSJJ	3760279731148
FILT'RAY ^{2G} Disposable Inline Water Filter – Sterile – 1 Month	AT030733	376027973FILTRAY2GSJJ	3760279730202
FILT'RAY ^{2G} Disposable Inline Water Filter – Sterile – 2 Months	AT030734	376027973FILTRAY2GSJJ	3760279730219
FILT'RAY ^{2G} Disposable Inline Water Filter – Sterile – 3 Months	AT030745	376027973FILTRAY2GSJJ	3760279731094
FILT'RAY ^{2G} Disposable Inline Water Filter – Sterile – 4 Months	AT030746	376027973FILTRAY2GSJJ	3760279731087

Gamme Filt'Ray 2.5G / *Filt'Ray 2.5G Range*

Product name	Article number	Basic UDI-DI	Code GTIN
Filt'Ray 1M sterile tap filter, shower flow	AT20150	376027973FILTRAY2.5GS47	03760279731476
Filt'Ray 1M sterile tap filter, straight flow	AT20151	376027973FILTRAY2.5GS47	03760279731490
Filt'Ray 1M sterile screw-in shower filter	AT20161	376027973FILTRAY2.5GS47	03760279731537
Filt'Ray 2M sterile tap filter, shower flow	AT20250	376027973FILTRAY2.5GS47	03760279731391
Filt'Ray 2M sterile tap filter, straight flow	AT20251	376027973FILTRAY2.5GS47	03760279731414
Filt'Ray 2M sterile screw-in shower filter	AT20261	376027973FILTRAY2.5GS47	03760279731452
Filt'Ray 3M sterile tap filter, shower flow	AT20350	376027973FILTRAY2.5GS47	03760279732176
Filt'Ray 3M sterile tap filter, straight flow	AT20351	376027973FILTRAY2.5GS47	03760279732169
Filt'Ray 3M sterile screw-in shower filter	AT20361	376027973FILTRAY2.5GS47	03760279732152
Filt'Ray 4M sterile tap filter, shower filter	AT20450	376027973FILTRAY2.5GS47	03760279732114
Filt'Ray 4M sterile tap filter, straight flow	AT20451	376027973FILTRAY2.5GS47	03760279732107
Filt'Ray 4M sterile screw-in shower filter	AT20461	376027973FILTRAY2.5GS47	03760279732091

Sont des dispositifs médicaux de classe Is conformes au **Règlement (UE) 2017/745**. L'évaluation de la conformité aux exigences Règlementaires a été menée par l'organisme notifié n° CE 0459, GMED SAS, selon l'Annexe IX Chapitre I et III.

*Are Class Is medical devices, complying with **Regulation (EU) 2017/745**. The compliance to the regulations has been checked by the notified body n° CE 0459, GMED SAS, according to the Appendix IX Chapter I and III.*

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 **certificat UE n°39236 rev.0** et les **dossiers techniques n° DTFILTRAY2GS et DTFILTRAY2.5GS**.

*Compliance with all applicable regulatory requirements for the medical devices is maintained by an **ISO 13485 certified quality management system** and is based on **EU Certificate n° 39236 rev. 0** and **technical documentations n° DTFILTRAY2GS and DTFILTRAY2.5GS**.*

Friville, le 09/02/2023

Patrick Delabie
Directeur Général – *General manager*

