

To whom it may concern,

24. Jul. 2025

NOTIFICATION OF CHANGE | Amends to PurMop and PurMop BLACK dry series

According to change no. 010_25CC

Dear Customer,

You are receiving this notification due to your prior purchase of below stated products. This notification fulfills our duty of informing our customers of relevant product changes for regularly delivered products. A description of the change is listed in the below table.

Specification	Character	Yes	No
	Technical Specifications		No change
	Raw material		No change
	Manufacturing process		No change
	Manufacturing site		No change
	Certification	Change	
	Packaging		No change
	Quality control		No change
	Labelling		No change
	Sterilisation	Change	
Change	Addition of a back-up sterilization site.		
Current	Vinagamma Ho Chi Minh City		
New	Vinagamma Da Nang and Vinagamma Ho Chi Minh City		
Reason for change	As part of the continuous improvement of our supply chain, a back-up sterilization site was added to improve the supply chain. The back-up sterilization service provider is a subsidiary of our current sterilization provider, which is an ISO 9001 and ISO 13485 qualified supplier. The product quality and current technical specifications remain unchanged. This change does not affect the product's performance or the suitability for its designated application. There is no change to the final product's manufacturing, decontamination, packaging, labeling or sterilization procedure. A dose mapping procedure was implemented according to ISO 11137. The certificate irradiation COI templates from both sterilization providers are shown in Annex 1.		
Notes	The period for the sending of change notification is shortened due to increase of production capacity. The back-up sterilisation service provider Vinagamma Da Nang will be used as a back-up supplier. Both sterilisation suppliers have their location in Vietnam.		
Effective date	This change will be implemented starting with Q4 2025 production onwards.		

Please contact us if more information is required on this issue, or if a supply of the above mentioned products cannot be accepted by you. If we do not receive further feedback from you within **30 days** from date of this letter, we will consider the above mentioned changes as accepted by you. The products will then be delivered without further notification.

Yours sincerely,



Dr. Adriana Ilie-Bertrams

Head of Product

Annex 1

Table 1. Concerned products

Item number	Item name
2111109	PurMop® EF40-S
2111118	PurMop® EFB40-S
2111105	PurMop® EC40-S
2111116	PurMop® EC40-S PLUS
2111111	PurMop® EC20-S
2111142	PurMop® EX40-S
2111144	PurMop® EXB40-S
2111155	PurMop® EF20-S
2112012	PurMop® EL40-S
2112024	PurMop BLACK® D1-S
2112026	PurMop BLACK® D3-SR
2112028	PurMop BLACK® D4-S
2112034	PurMop BLACK® ID9-S
2112046	PurMop BLACK® F1-S
2112055	PurMop BLACK® D3-S
2112058	PurMop BLACK® D1-SH

Figure 1. COI template current sterilization provider,



**RESEARCH AND DEVELOPMENT CENTER FOR RADIATION TECHNOLOGY
-VINAGAMMA-**
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04-7.5.1-02

CERTIFICATE OF IRRADIATION
No.: 04/VINAGAMMA-HYDROFLEX

VINAGAMMA certifies that the following products were treated by gamma irradiation at its plant in accordance with:
EN ISO 11137-1:2006/Amd.2:2018 Sterilization of Health Care Products
EN ISO 9001:2015 Quality Management System

Consigner : **Hydroflex Group GmbH**
Address : Kiesacker 19, D-35418 Buseck, Germany
Name of products :

Art. No	Article description	Carton size(cm)	Batch No.	Qty (pcs)	Qty (bag)
2111105	PurMop ® EC40-S	42x29x35cm	1224114E12	16,000	3,200

Date of treatment: 01-Jan-2025
Set Dmin: 27.5 kGy
Set Dmax: 39.0 kGy
Irradiation time: 20 hrs 33 mins
Actual Dmin: 27.6 kGy
Dmax according to DUR: 37.3 kGy
Expiry date: 30-Nov-2026

Treatment purpose: ☐ Pasteurization ☒ Sterilization

04-7.5.1-02

CERTIFICATE OF IRRADIATION
No.: 111/VINAGAMMA-HYDROFLEX

VINAGAMMA certifies that the following products were treated by gamma irradiation at its plant in accordance with:
EN ISO 11137-1:2006/Amd.2:2018 Sterilization of Health Care Products
EN ISO 9001:2015 Quality Management System

Consigner : **Hydroflex Group GmbH**
Address : Kiesacker 19, D-35418 Buseck, Germany
Name of products :

Art. No	Article description	Carton size(cm)	Batch No.	Qty (pcs)	Qty (bag)
2111118	PurMop ® EFB40-S	42x29x40cm	0125008E7	8,000	1,600

Date of treatment: 22-Jan-2025
Set Dmin: 27.5 kGy
Set Dmax: 39.0 kGy
Irradiation time: 20 hrs 41 mins
Actual Dmin: 27.8 kGy
Dmax according to DUR: 37.5 kGy
Expiry date: 31-Dec-2026

Treatment purpose: ☐ Pasteurization ☒ Sterilization


 <small>ISO 9001:2015 ISO 13485: 2016</small>	RESEARCH AND DEVELOPMENT CENTER FOR RADIATION TECHNOLOGY -VINAGAMMA- Address: 202A Street 11, Linh Xuan Ward, Thu Duc City, Ho Chi Minh City, Vietnam Tel: 84-28-38975922 Email: vinagamma@vinagamma.com.vn Web: www.vinagamma.com.vn				
04-7.5.1-02					
CERTIFICATE OF IRRADIATION No.: 1041/VINAGAMMA-HYDROFLEX					
VINAGAMMA certifies that the following products were treated by gamma irradiation at its plant in accordance with: EN ISO 11137-1:2006/Amd.2:2018 Sterilization of Health Care Products EN ISO 9001:2015 Quality Management System					
Consigner : Hydroflex Group GmbH Address : Kiesacker 19, D-35418 Buseck, Germany Name of products :					
Art. No	Article description	Carton size(cm)	Batch No.	Qty (pcs)	Qty (bag)
2111155	PurMop ® EF20-S	41x20x29cm	1024099E50	14,200	7,100
Date of treatment: 04-Oct-2024 Set Dmin: 27.5 kGy Set Dmax: 39.0 kGy Irradiation time: 20 hrs 05 mins Actual Dmin: 27.7 kGy Dmax according to DUR: 37.4 kGy Expiry date: 30-Sep-2026 Treatment purpose: <input type="checkbox"/> Pasteurization <input checked="" type="checkbox"/> Sterilization					

Figure 2. COI template new sterilization provider

Products PurMop® EFB40-S, PurMop® EC40-S and PurMop® EF20-S used for dose mapping protocol

 <small>ISO 9001:2015 ISO 13485: 2016</small>	RESEARCH AND DEVELOPMENT CENTER FOR RADIATION TECHNOLOGY -VINAGAMMA- Address: 202A Street 11, Linh Xuan Ward, Thu Duc City, Ho Chi Minh City, Vietnam Tel: 84-28 -38975922 Email: vinagamma@vinagamma.com.vn Web: www.vinagamma.com.vn				
04-7.5.1-02					
CERTIFICATE OF IRRADIATION No.: 01/VINAGAMMA_DN-HYDROFLEX					
VINAGAMMA certifies that the following products were treated by gamma irradiation at its plant in accordance with: EN ISO 11137-1:2006/Amd.2:2018 Sterilization of Health Care Products EN ISO 9001:2015 Quality Management System					
Consigner : Hydroflex Group GmbH Address : Kiesacker 19, D-35418 Buseck, Germany Name of products :					
Art. No	Article description	Carton size(cm)	Batch No.	Qty (pcs)	Qty (bag)
2111118	PurMop ® EFB40-S	42x29x40cm	0325023E7	15,000	3,000
Date of treatment: 28-Mar-2025 Set Dmin: 27.5 kGy Irradiation time: 47 hrs 30 mins Actual Dmin: 27.6 kGy Expiry date: 28-Feb-2027 Treatment purpose: <input type="checkbox"/> Pasteurization <input checked="" type="checkbox"/> Sterilization					

 <small>ISO 9001:2015 ISO 13485: 2016</small>	RESEARCH AND DEVELOPMENT CENTER FOR RADIATION TECHNOLOGY -VINAGAMMA- Address: 202A Street 11, Linh Xuan Ward, Thu Duc City, Ho Chi Minh City, Vietnam Tel: 84-28 -38975922 Email: vinagamma@vinagamma.com.vn Web: www.vinagamma.com.vn				
04-7.5.1-02					
CERTIFICATE OF IRRADIATION No.: 03/VINAGAMMA_DN-HYDROFLEX					
VINAGAMMA certifies that the following products were treated by gamma irradiation at its plant in accordance with: EN ISO 11137-1:2006/Amd.2:2018 Sterilization of Health Care Products EN ISO 9001:2015 Quality Management System					
Consigner : Hydroflex Group GmbH Address : Kiesacker 19, D-35418 Buseck, Germany Name of products :					
Art. No	Article description	Carton size(cm)	Batch No.	Qty (pcs)	Qty (bag)
2111105	PurMop ® EC40-S	42x29x35cm	0425036E12	1,600	320
Date of treatment: 28-Mar-2025 Set Dmin: 27.5 kGy Irradiation time: 47 hrs 30 mins Actual Dmin: 27.6 kGy Expiry date: 31-Mar-2027 Treatment purpose: <input type="checkbox"/> Pasteurization <input checked="" type="checkbox"/> Sterilization					



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04-7.5.1-02

CERTIFICATE OF IRRADIATION

No.: 02/VINAGAMMA_DN-HYDROFLEX

VINAGAMMA certifies that the following products were treated by gamma irradiation at its plant in accordance with:
EN ISO 11137-1:2006/Amd.2:2018 Sterilization of Health Care Products
EN ISO 9001:2015 Quality Management System

Consigner : **Hydroflex Group GmbH**
Address : Kiesacker 19, D-35418 Buseck, Germany
Name of products :

Art. No	Article description	Carton size(cm)	Batch No.	Qty (pcs)	Qty (bag)
2111155	PurMop ® EF20-S	41x20x29cm	0325030E50	19,000	9,500

Date of treatment: 28-Mar-2025
Set Dmin: 27.5 kGy
Irradiation time: 47 hrs 30 mins
Actual Dmin: 27.5 kGy
Expiry date: 28-Feb-2027

Treatment purpose: ☐ Pasteurization ☒ Sterilization