

COMMUNICATION OF 12 MARCH 2021

OBJECT: SUSPECTED STERILIZATION NON-COMPLIANCE

Dear Customer,

Following the attached communication of Steril Milano, a sterility check must be carried out on batches subjected to sterilisation processes at the plant mentioned above.

We asks you to immediately block the sale of all products in the following list and forward the same request to your sub-distributors / customers.

n° doc	/A	Date of delivery		Code	Lot	Q.ty	EXPIRING DATE
305		17/03/17	HUM-MED d.o.o.	VVJT0810	117	150	feb-22
1340		16/11/16	HUM-MED d.o.o.	VVJT0810	2816	150	ago-21
1103		29/09/16	HUM-MED d.o.o.	VVJT0810	2816	50	ago-21
1286		29/09/17	HUM-MED d.o.o.	VVJT0810	3617	150	ago-22
179		28/02/18	HUM-MED d.o.o.	VVJT0810	4817	150	ott-22
4		09/01/18	HUM-MED d.o.o.	VVJT0810	4817	150	ott-22
903		10/07/17	HUM-MED d.o.o.	VVJT0810	2117B	150	apr-22

We ask you to send us the inventory of such products and to collect the inventory information from your sub-distributors / customers up to the users within 24 working hours from receipt of this notice, and to make sure that all products will not be used under any circumstances.

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VIGEO SRL will investigate the sterility of all batches of sterilization and no batch will be unlocked without having received positive results of sterility from the laboratory of analysis whose implementation times have yet to be defined.

After the receipt of sterility tests, We will communicate the outcome to allow the definition of further actions to be taken.

We appreciate your attention and we apologize for any inconvenience caused.

For any questions or concerns regarding this recall, please contact us at the following contact:

corporateaffairs@vigeosrl.it

VIGEO s.r.l.

Sede Operativa: Via Dell'Alpino 2 , 46031 BAGNOLO S.VITO (MN) - ITALY

Sede Legale: via Carlo Poma 19/B, 46034 BORGO VIRGILIO (MN)

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Matteo Negrini
VIGEO

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