

ADVISORY NOTICE

ELite H Clean – sealing pad deterioration

Date: July 20th, 2022
ID: AN_2022/17
Product: **ELite H Clean**
Cat. No.: HEM00023

List of affected lots:

Product	Cat. No.	Lot number	Expiration
ELite H Clean	HEM00023	20220402	2024-04-01

Advised actions to be taken by Customer:

- Do not use and quarantine ELite H Clean lot 20220402.
- Discard all unused affected products in your inventory.
- Contact your local Erba Representative to replace you all affected products by different lot.
- Please forward this notice to all those who need to be aware within your organization.
- Other lots of ELite H Clean are OK for usage

Description:

ELite H Clean, lot 20220402 contains sealing pad which is facing deterioration in time and can cause contamination of Elite H Clean solution and consequently contamination of hydraulic system of your haematology analyser. Other lots on market are free of this defect.



Erba Lachema s.r.o.



Please inform all users of the affected products immediately.

We ask customers outside the EU to handle necessary announcements to authorities in their countries.

Under current regulations, we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason, we would like to ask you to fill in, sign the attached confirmation, and communicate this information to all concerned customers. Please send it back to Erba Lachema by e-mail until **August 31st 2022**.

Please accept our sincere apologies for the inconvenience caused. In case you have any questions, please do not hesitate to contact us.

Best regards,

Erba Lachema, s.r.o.

Erba Lachema s.r.o.
Karásek 2219/1d, 621 00 Brno
DIČ: CZ26918846 -22-

Radim Herrmann
Quality Manager

<mailto:r.herrmann@erbamannheim.com>

Confirmation of receipt

Please, confirm that the customer information below has been received by your facility.

ID: AN_2022/17
Name: ELite H Clean – sealing pad deterioration
Product: ELite H Clean
Cat. No.: HEM00023

Herewith I confirm that we have received above mentioned customer notification and that all required actions have been implemented and all concerned parties have been informed about this Advisory Notice. The use and further distribution of the affected products has been stopped.

Customer name:

Confirmed by:
(name and position)

Date and sign:

Please complete this form and send it back via email until **August 31st 2022**.

Thank you for your efforts.

Erba Lachema, s.r.o.

Radim Herrmann
Quality Manager
<mailto:r.herrmann@erbamannheim.com>