

## ADVISORY NOTICE

### ELite H Clean – sealing pad deterioration

Date: July 20<sup>th</sup>, 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 31<sup>st</sup> 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.**  
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DIČ: CZ26918846 -22-

Radim Herrmann  
Quality Manager

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**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 31<sup>st</sup> 2022.**

Thank you for your efforts.

Erba Lachema, s.r.o.

Radim Herrmann  
Quality Manager  
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