Erba Lachema s.r.o.

ADVISORY NOTICE

21_2026_Updated Installation Requirements for Erba Lachema Analysers

This is to inform our distributors and customers about an update to the installation and service requirements applicable to our analyser portfolio.
The update introduces a risk-based approach differentiating between fully automated and semi-automated analysers, while maintaining compliance with applicable regulatory requirements, including ISO 13485 and Regulation (EU) 2017/746 (IVDR).

Background and rationale
As a part of our continuous improvement process and commitment to regulatory compliance, we have reviewed our installation and maintenance processes to ensure they remain appropriate for the intended use, complexity, and risk profile of each analyser type.

Based on this assessment, our analysers have been categorized into two groups:

- **Fully Automated Analysers**
- **Semi-Automated Analysers**

This approach allows us to apply appropriate controls according to device complexity while ensuring that installation activities, performance verification, and service activities remain adequately documented and traceable.

1. Fully Automated Analysers

For fully automated analysers, installation and preventive maintenance activities shall only be performed by personnel who have successfully completed the required training provided by our company.

The following training pathways are available:

- **Face-to-face training** performed by qualified company service engineers.
- **Training at our dedicated training centres** located in Dubai or Mumbai.
- **Online training** provided through approved training channels.
- **Qualification quiz** for personnel who have previous experience installing these analyser types but have not previously completed formal company training (trained by one of the qualified engineers from the same organisation).

Only personnel who have completed one of the approved qualification pathways are considered authorized to perform installation and preventive maintenance activities.

Installation documentation requirements
For every installation of a fully automated analyser:

- An installation protocol must be completed.
- The completed installation protocol must be uploaded and linked to the respective instrument record within the CRM Install Base.

- Installation records must ensure full traceability of the device installation history.

The same documentation and qualification requirements apply to preventive maintenance activities.

2. Semi-Automated analysers

For semi-automated analysers, installation by formally trained company personnel is not mandatory.

However, installation must be performed strictly according to the applicable User Manual, and all defined installation and acceptance requirements must be followed.

Upon completion of installation, the responsible party must confirm in the CRM Install Base that:

- The analyser has been installed according to the User Manual.
- Precision check has been performed, and acceptance criteria have been met.
- No issues were observed during installation.
- Accuracy check has been performed, and acceptance criteria have been met.

These confirmations ensure appropriate verification of device performance and maintain traceability within our quality management system.

Applicable semi-automated analysers:

Part numbers	Catalogue numbers	Name
50007132	INS00013	Chem 5 v3
52000103	INS00014	CHEM-7 - ECZ
50003508	INS00064	LAURA SMART
50005205	INS00063	LAURA
50001529	INS00062	DENSILAMETER II.
50004880	INS00072	Erba Scan
52000131	INS00032	ERBA LISA WASH
50005168	INS00059	ECL 105
10020690	INS00079	EC 90
50005172	INS00014	CHEM-7
10020904	VET00001	EC 90 VET
52000121	TBMD44001	LisaScan EM
50007187	INS00023	ERBA LYTE PLUS (NA/K/CL-110/220V)
50008058	INS00014	CHEM-7 WITH INCUBATOR
50005169	INS00060	ECL 412

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Impact on Distributors and Customers

This updated approach provides increased flexibility for distributors while maintaining the necessary regulatory controls required for safe and effective use of our devices.

The revised process:

- Ensures installation activities remain appropriate to device complexity and risk.
- Maintains compliance with ISO 13485 quality management system requirements.
- Supports compliance with IVDR requirements related to device performance, traceability, and control of service activities.
- Reduces unnecessary operational burden while preserving product quality and patient safety.

All existing requirements related to proper device handling, installation, verification, documentation, and reporting of issues remain unchanged.

We appreciate your cooperation in implementing this updated process and ensuring that all activities are performed according to the applicable requirements.

Best regards,

Psshettigar

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