

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Erba Lachema s.r.o.

Karásek 2219/1d

62100 Brno

Czech Republic


Holds Certificate Number:

MD 745529

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design and development, manufacture and distribution of in vitro diagnostics medical device instruments, reagents, calibrators and control materials for clinical chemistry, immunology, microbiology, hematology, hemostasis, and urine analysis.
Installation and servicing of In Vitro Diagnostics instruments.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2021-08-03

Latest Revision Date: 2024-10-29

Effective Date: 2024-12-02

Expiry Date: 2027-12-01

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