

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, development, production and sales of in vitro diagnostics medical devices according to own and customer requirements.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-08-03

Latest Revision Date: 2022-05-23

Effective Date: 2021-12-02

Expiry Date: 2024-12-01

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