EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 745525 R000

Manufacturer: Erba Lachema s.r.o.

Address:
Karásek 2219/1d
62100 Brno
Czech Republic

Single Registration Number: CZ-MF-000024067

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-09-26**

Current Issue Date: **2024-09-26**

Starting Validity Date: **2024-09-26**

Expiry Date: **2029-09-25**

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Device Schedule: Class D, C and B devices

Class B devices	**Intended purpose**
IVR 0608 – Devices intended to be used for screening, determination or monitoring of physiological markers	In vitro diagnostic device instruments, reagents, test strips, calibrators and controls, intended to be used for screening, determination or monitoring of physiological markers.
Class C devices	**Intended purpose**
W0101 – Clinical Chemistry IVP 3002 – In vitro diagnostic devices which require knowledge regarding biochemistry.	Clinical chemistry reagents, calibrators and controls intended for screening, determination or monitoring of physiological markers.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3393856	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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