

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:

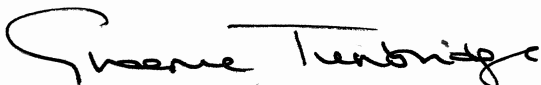
Karásek 2219/1d
62100 Brno
Czech Republic

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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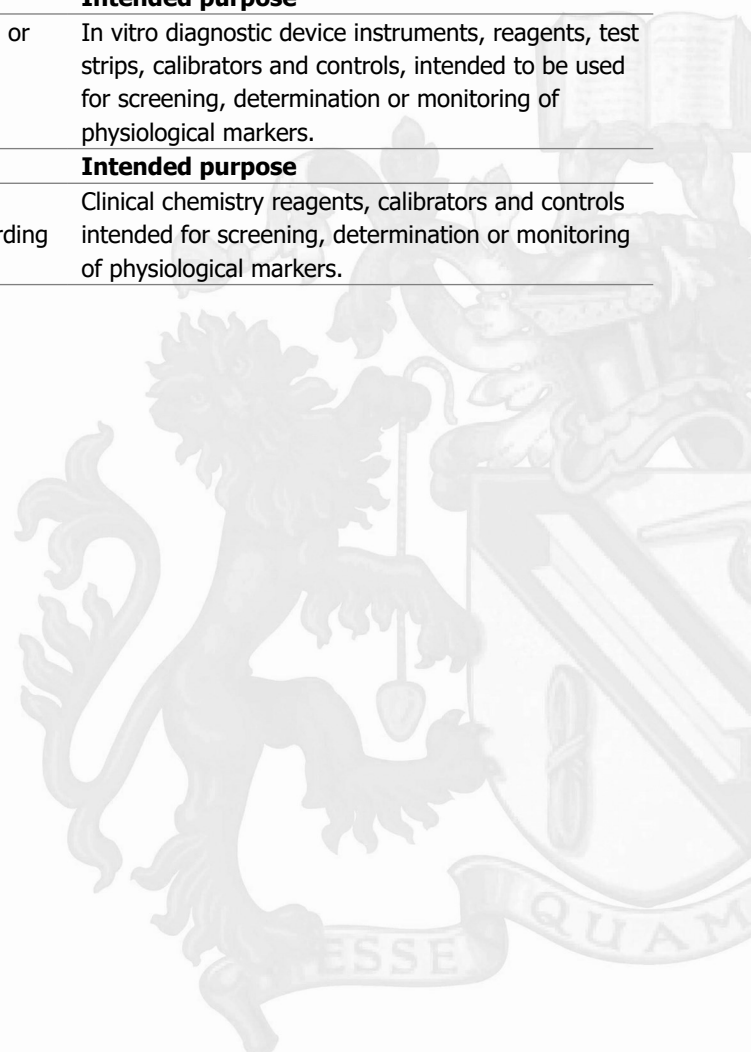
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Device Schedule: Class D, C and B devices

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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