

EU Quality Management System Certificate

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

Manufacturer:

ARCHImedline GmbH

Leberstrasse 20/2

Vienna 1110

Austria

Single Registration Number: AT-MF-000037501

Certificate ID: IQMS/00010/0v002

Issue date: 27. July 2026

Valid from: 09. July 2026

Expiry date: 08. July 2031

Report No.: 2296-1494-105-01

The Notified Body QMD Services GmbH declares that the requirements of Annex IX, Chapter I and III of the Regulation (EU) 2017/746 have been met for the listed products. The assessment has proven that the manufacturer has established and applies a Quality Management System which is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation (EU) 2017/746. 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 QMD Services GmbH, a Notified Body for the above mentioned regulation:



Anni Koubek
CEO



Florian Heffeter
CEO





QMD Services GmbH
Zelinkagasse 10/3
1010 Wien Austria

www.qmdservices.com

Notified Body
according to
Regulation (EU)
2017/746 on
in vitro diagnostic
medical devices

Notified Body
identification no.:
2962

Products

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Class B

Categories of devices and intended purpose

IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease.

The validity of this certification depends on conditions and/or is limited to the following: -none-





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Certificate History

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Version	Description	Issue Date
001	Initial certification 1641-1494-101	09. July 2026
002	Scope extension 2296-1494-105-01 for additional 7 Class B devices	27. July 2026

