QMD Services
Quality | Medical | Devices

BECAUSE PATIENT SAFETY MATTERS.

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

EU Quality Management System Certificate

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

Certificate ID: IQMS/00010/0v001

Issue date: 09. July 2026
Valid from: 09. July 2026
Expiry date: 08. July 2031
Report No.: 1641-1494-101

Manufacturer:

ARCHImedline GmbH

Leberstrasse 20/2
Vienna 1110
Austria
Single Registration Number: AT-MF-000037501

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

e08184b8-7cec-48a6-bbb2-8f1391e880e9

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

Certificate ID: IQMS/00010/0v001

Issue date: 09. July 2026
Valid from: 09. July 2026
Expiry date: 08. July 2031
Report No.: 1641-1494-101

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-

fd0d85cc-78da-4f8e-950d-b0098dfb8552

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

Certificate History

Certificate ID: IQMS/00010/0v001

Issue date: 09. July 2026
Valid from: 09. July 2026
Expiry date: 08. July 2031

Version	Description	Issue Date
001	Initial certification 1641-1494-101	09. July 2026

0872185f-2316-4206-8ecd-0218b69968ad