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/00009/0v001

Issue date: 06. July 2026
Valid from: 06. July 2026
Expiry date: 05. July 2031
Report No.: 1611-1525-101

Manufacturer:

Pharmaline Sağlık Hizmetleri SAN. TİC. A.Ş.

Sahrayıcedid Mh. Atatürk Caddesi
Atatürk Cadde Konutları No:43
A-Blok Daire:6 34734 Kadıköy/Istanbul
Turkey

Single Registration Number: TR-MF 000019285

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

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Products

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Class C

Generic device groups (EMDN code 3rd level & IVP code)	**Intended purpose**
W0105 - Infectious Diseases 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

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

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Certificate History

Certificate ID: IQMS/00009/0v001

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Version	Description	Issue Date
001	Initial certification 1611-1525-101	06. July 2026

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