QMD Services
Quality | Medica | 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/00003/0v001

Issue date: 18. September 2024
Valid from: 18. September 2024
Expiry date: 17. September 2029
Report No.: 1653-1207-101

Manufacturer:

MacroArray Diagnostics GmbH
Lemböckgasse 59, Top 4
1230 Wien
Austria
Single Registration Number: AT-MF-000030541

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	Intended purpose
W0102 - Immunochemistry (Immunology) IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays	IVR 0603 - Devices intended to be used for screening, confirmation/determination or monitoring of allergies and intolerances
W0201 - Chemistry / Immunochemistry instruments IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays	IVR 0603 - Devices intended to be used for screening, confirmation/determination or monitoring of allergies and intolerances

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/00003/0v001

Issue date: 18. September 2024
Valid from: 18. September 2024
Expiry date: 17. September 2029

Version	Description	Issue Date
001	Initial certification 1653-1207-101	18. September 2024

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ES kokybės valdymo sistemos sertifikatas

Reglamentas (ES) 2017/745, I ir III skyriai, Priedas IX

Sertifikato ID: IQMS/00003/0 v001

Išleidimo data: 2024 m. rugsėjo 18 d.
Galioja nuo: 2024 m. rugsėjo 18 d.
Galioja iki: 2029 m. rugsėjo 17 d.
Ataskaitos Nr.: 1653-1207-101

Gamintojas:

MacroArray Diagnostics GmbH

Lemböckgasse 59, Top 4
1230
Viena
Austrija
Bendrasis registracijos numeris: AT-MF-000030541

Notifikuotoji įstaiga „QMD Services GmbH" pareiškia, kad išvardyti produktai atitinka Reglamento (ES) 2017/746 IX priedo I ir III skyrių reikalavimus. Vertinimas parodė, kad gamintojas sukūrė ir taiko kokybės valdymo sistemą, kuriai atliekama periodinė priežiūra, kaip reikalaujama aktualiam atitikties vertinimui pagal Reglamentą (ES) 2017/746. Norint pateikti į rinką D klasės prietaisus ir savikontrolės testus, pacientų naudojamus bandomuosius ir pagalbinius diagnostikos prietaisus, reikalingas IX priedo II skyriaus sertifikatas.

Minėto reglamento notifikuotosios įstaigos „QMD Services GmbH" vardu:

Anni Koubek
generalinė

Florian Heffeter
generalinis