

DECLARATION OF CONFORMITY

Manufacturer MacroArray Diagnostics GmbH (MADx)
Lemböckgasse 59, Top 4
1230 Vienna, Austria

SRN AT-MF-000030541

We declare that this EU declaration of conformity is issued under our sole responsibility and that the below mentioned in vitro diagnostic medical devices meet all the provisions of the Regulation (EU) 2017/746 and the applicable legislation which apply to it.

Products: See Annex 1

Intended Purpose: See Annex 1

Conformity Assessment: Annex IX, chapter I + III

Notified Body: QMD Services GmbH

Notified Body Number: 2962

Certificates Issued by Notified Body: EN ISO 13485: registration no. M-00266/0
EU QMS certificate: IQMS/00003/0 v002

Applicable Legislation: The in vitro diagnostic medical devices described above are in conformity with the following legislations:
Regulation (EU) 2017/746
The following standards have been applied:
EN ISO 9001:2015, EN ISO 13485:2016 + AC:2018 + A11:2021, EN 13612:2002, EN 13641:2002, EN ISO 14971:2019, EN ISO 15223-1:2022-02, EN ISO 17511:2020, EN ISO 18113-1:2022, EN ISO 18113-2:2022, EN ISO 18113-3:2022, EN ISO 20417:2021, EN ISO 20916:2021, EN ISO 23640:2015, EN 61010-2-101:2017, EN 61326-2-6:2013, EN 62304:2006, IEC 62304:2006 + A1:2015, IEC 62366-1:2015 + COR1:2016 + A1:2020

Vienna, Austria
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Document Change History

Version	Description	Replaces
1.0	Initial version for the IVDR.	-
2.0	EU QMS Certificate number was updated.	1.0
3.0	No changes in the content of the document, but the document is now based on an officially approved template.	2.0

Annex 1

Product	REF	Risk Classification & Rule	Intended Purpose	Basic UDI-DI	UDI-DI
RAPTOR SERVER Analysis Software	22-0000-01	Class C, implementing rule 1.4	The RAPTOR SERVER Analysis Software drives and influences MADx processing systems in combination with ALEX technology-based products. The software analyzes the output from ALEX technology-based arrays and is used by trained laboratory personnel and medical professionals in a medical laboratory.	91201229222JW	9120122922200