

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

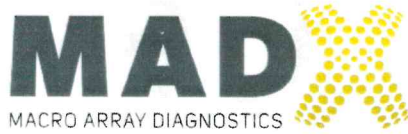
Conformity Assessment: In accordance with Reg. (EU) 2017/746 Article 48 (10) and Annex II+III

Notified Body: N/A

Notified Body Number: N/A

Certificates Issued by Notified Body: N/A

Applicable Legislation: The in vitro diagnostic medical devices described above are in conformity with the following legislations:
Regulation (EU) 2017/746



Vienna, Austria
20.05.2026

Dr. Christian Harwanegg,
Chief Executive Officer,
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Document Change History

Version	Description	Replaces
1.0	Initial version for the IVDR according to ÄA – 24042020.	-
2.0	Translation, SRN added.	1.0
3.0	Applicable Legislation, CE Marking added, translation moved to another document.	2.0
4.0	No changes in the content of the document, but the document is now based on an officially approved template.	3.0



Annex 1

Product	REF	Risk Classification & Rule	Intended Purpose	Basic UDI-DI	UDI-DI
MAX 9k	17-0000-01	Class A, Rule 5b	The MAX 9k is an instrument and intended as accessory to ALEX technology-based products. The IVD medical product automatically processes up to 10 ALEX technology-based arrays in one run and acquires pictures of those. It is used by trained laboratory personnel and medical professionals in a medical laboratory.	91201229217K5	9120122921708