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CE

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

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Vienna, Austria
20.05.2026

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Dr. Christian Harwanegg,
Chief Executive Officer,
MacroArray Diagnostics GmbH

Document Change History

Version	Description	Replaces
1.0	Initial version of the document for IVDR, according to ÄA – 4042020.	-
2.0	Translation, SRN added.	1.0
3.0	Applicable Legislation, CE Marking added, translation moved to another document.	2.0
4.0	The Intended Purpose was corrected.	3.0
5.0	No updates in the content, but the document is now based on an officially approved template.	4.0

Annex 1

Product	REF	Risk Classification & Rule	Intended Purpose	Basic UDI-DI	UDI-DI
MAX 45k	16-0000-01	Class A, Rule 5b	The MAX 45k is an instrument and intended as accessory to ALEX technology-based products. The IVD medical product automatically processes ALEX technology-based arrays and acquires pictures of those. The product is used by trained laboratory personnel and medical professionals in a medical laboratory.	91201229216K3	9120122921609