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MADX
MACRO ARRAY DIAGNOSTICS

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

Document Change History

Version	Description	Replaces
1.0	Initial version and rework for the IVDR according to the ÄA-24042020.	-
2.0	German translation, SRN added.	1.0
3.0	Intended Purpose added.	2.0
4.0	Applicable Legislation and CE marking added, translation moved to another document.	3.0
5.0	No changes in the content of the document, but an update as 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
ImageXplorer	11-0000-01	Class A, Rule 5b	The ImageXplorer is an instrument and intended as accessory to ALEX technology-based products. The IVD medical product acquires pictures of the ALEX technology-based arrays and is used by trained laboratory personnel and medical professionals in a medical laboratory.	91201229211JR	9120122921104