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MADX
MACRO ARRAY DIAGNOSTICS

CE 2962

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

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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 for the IVDR.	-
2.0	EU QMS Certificate Number was updated.	1.0
3.0	No change 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
ALEX² Allergy Xplorer *consisting of:* 20x ALEX² Cartridges 2 x 50 mL Washing Solution 1 x 9 mL ALEX² Sample Diluent 1 x 11 mL ALEX² Detection Antibody 1 x 11 mL ALEX² Substrate Solution 1 x 2.4 mL Stop Solution	02-2001-01	Class C, Rule 3e	The ALEX² Allergy Xplorer is a test kit used for in-vitro examination of human serum or plasma (exception EDTA-plasma) to provide information to aid the diagnosis of patients suffering from IgE-mediated diseases in conjunction with other clinical findings or diagnostic test results. The IVD medical device detects allergen-specific IgE (sIgE) quantitatively and total IgE (tIgE) semi-quantitatively. The product is used by trained laboratory personnel and medical professionals in a medical laboratory.	91201229202JQ	9120122920220
ALEX² Allergy Xplorer *consisting of:* 50x ALEX² Cartridges 1 x 250 mL Washing Solution 4x conc 1 x 30 mL ALEX² Sample Diluent 1 x 30 mL ALEX² Detection Antibody 1 x 30 mL ALEX² Substrate Solution 1 x 10 mL Stop Solution	02-5001-01				9120122920251