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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:	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.	-
2.0	The content of the document does not change, but the document is now based on an officially approved template.	1.0

Annex 1

Product	REF	Risk Classification & Rule	Intended Purpose	Basic UDI-DI	UDI-DI
ALEX Food *consisting of:* 50x ALEX Food Cartridges 1 x 250 mL Washing Solution 4x conc 1 x 30 mL ALEX Food Sample Diluent 1 x 30 mL ALEX Food Detection Antibody 1 x 30 mL ALEX Food Substrate Solution 1 x 10 mL Stop Solution	07-5001-01	Class C, Rule 3e	The ALEX Food test system is a quantitative in vitro diagnostic test for the measurement of 59 allergen specific IgE (sIgE) food allergens and a semi-quantitative in vitro diagnostic test for the measurement of total IgE (tIgE) in human serum or plasma (exception EDTA-plasma). It is to be used by clinical chemistry laboratories, trained laboratory personnel and medical professionals for the purpose of supporting the clinical diagnosis of IgE mediated diseases, in conjunction with other clinical findings or diagnostic test results. The test is intended for MAX 45k and MAX 9k only.	91201229207K2	9120122920756