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MADX
MACRO ARRAY DIAGNOSTICS

CE 2962

# DECLARATION OF CONFORMITY

| | |
|---|---|
| **Manufacturer** | MacroArray Diagnostics GmbH (MADx)<br>Lemböckgasse 59, Top 4<br>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:<br>Regulation (EU) 2017/746<br>The following standards have been applied:<br>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

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

| Version | Description | Replaces |
|---|---|---|
| 1.0 | Initial version. | - |
| 2.0 | No change in the content of the document, 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 Air *consisting of:*<br>50x ALEX Air Cartridges<br>1 x 250 mL Washing Solution 4x conc<br>1 x 30 mL ALEX Air Sample Diluent<br>1 x 30 mL ALEX Air Detection Antibody<br>1 x 30 mL ALEX Air Substrate Solution<br>1 x 10 mL Stop Solution | 06-5001-01 | Class C, Rule 3e | The ALEX Air test system is a quantitative in vitro diagnostic test for the measurement of 59 allergen specific IgE (sIgE) of inhalative allergens and a semi-quantitative in vitro diagnostic test for the measurement of total IgE (tIgE) in human serum or plasma (exception EDTA plasma).<br>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. | 91201229206JY | 9120122920657 |