

## 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

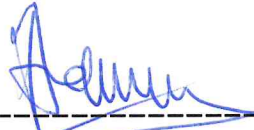
**Applicable Legislation:** The in vitro diagnostic medical devices described above are in conformity with the following legislations:

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

Vienna, Austria  
20.05.2026



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**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
<p>ALEX<sup>2</sup> Allergy Xplorer consisting of:            20x ALEX<sup>2</sup> Cartridges            2 x 50 mL Washing Solution            1 x 9 mL ALEX<sup>2</sup> Sample Diluent            1 x 11 mL ALEX<sup>2</sup> Detection Antibody            1 x 11 mL ALEX<sup>2</sup> Substrate Solution            1 x 2.4 mL Stop Solution</p>	02-2001-01	Class C, Rule 3e	<p>The ALEX<sup>2</sup> 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.</p> <p>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.</p>	91201229202JQ	9120122920220
<p>ALEX<sup>2</sup> Allergy Xplorer consisting of:            50x ALEX<sup>2</sup> Cartridges            1 x 250 mL Washing Solution 4x conc            1 x 30 mL ALEX<sup>2</sup> Sample Diluent            1 x 30 mL ALEX<sup>2</sup> Detection Antibody            1 x 30 mL ALEX<sup>2</sup> Substrate Solution            1 x 10 mL Stop Solution</p>	02-5001-01	9120122920251			