



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 v001

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, 20.09.2024

Dr. Christian Harwanegg, CEO of MADx

Document Change History

Version	Description	Replaces
1.0	New compilation for IVDR	Former version

Annex 1

Product	REF	Risk Classification & Rule	Intended Purpose	Basic UDI-DI	UDI-DI
<p>ALEX² Allergy Xplorer Consisting of 20 x ALEX² Cartridges 2 x 50 ml ALEX² 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 ALEX² Stop Solution</p>	02-2001-01	Class C, Rule 3e	<p>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.</p>	91201229202JQ	9120122920220
<p>ALEX² Allergy Xplorer Consisting of 50 x ALEX² Cartridges 1 x 250 ml ALEX² 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 ALEX² Stop Solution</p>	02-5001-01	Class C, Rule 3e	<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	9120122920251