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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

Vienna, 17.12.2024

Dr. Christian Harwanegg, CEO of MADx

Document Change History

Version	Description	Replaces
1.0	First compilation	-

Annex 1

Product	REF	Risk Classification & Rule	Intended Purpose	Basic UDI-DI	UDI-DI
ALEX³ Allergy Xplorer Consisting of 20 x ALEX³ Cartridges 2 x 50 ml Washing Solution 1 x 9 ml ALEX³ Sample Diluent 1 x 11 ml ALEX³ Detection Antibody 1 x 11 ml ALEX³ Substrate Solution 1 x 2.4 ml Stop Solution	03-2001-01	Class C, Rule 3e	ALEX³ 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) quantitatively in the range from 2 - 1000 kU/l (semi-quantitative 1001-2500 kU/l). The product is used by trained laboratory personnel and medical professionals in a medical laboratory.	91201229203JS	9120122920329
ALEX³ Allergy Xplorer Consisting of 50 x ALEX³ Cartridges 1 x 250 ml Washing Solution 4x conc 1 x 30 ml ALEX³ Sample Diluent 1 x 30 ml ALEX³ Detection Antibody 1 x 30 ml ALEX³ Substrate Solution 1 x 10 ml Stop Solution	03-5001-01	Class C, Rule 3e		91201229203JS	9120122920350