



# DECLARATION OF CONFORMITY

Manufacturer: MacroArray Diagnostics (MADx)  
Lemböckgasse 59, Top 4  
1230 Vienna, Austria

SRN: AT-MF-000030541

We declare that this 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 Directive 98/79/EC and the applicable legislation which apply to it.

Products: See Annex 1

Intended Purpose: See Annex 1

Classification: Other Device

Applicable Legislation: The vitro diagnostic medical devices described above are in conformity with the following legislations: Directive 98/79/EC, Regulation (EC) 765/2008



Macro Array Diagnostics GmbH  
Lemböckgasse 59 / Top 4 - 1230 Wien

M: office@macroarraydx.com • P: +43 (0)1 865 25 73  
UID: ATU70451059 • FN 448974 g

www.macroarraydx.com

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Dr. Christian Harwanegg, CEO of MADx

## Document Change History

Version	Description	Replaces
01	First compilation	Former version
02	Name korrigiert	01
03	Neue Adresse gemäß AA_16122019 MADx Umzug in neue Facility und hinzufügen der neuen ALEX <sup>2</sup> Variante gemäß AA_16122019 Neue ALEX <sup>2</sup> Variante für MAX (50 Analysen)	02
04	Tippfehler (Sample Diluent doppelt) korrigiert, klarere Ausführung der beiden ALEX <sup>2</sup> Varianten	03
05	Neues ISO Zertifikat hinzugefügt, Ablaufdatum verlängert	04
06	4x conc bei Washing Solution der 50er Variante hinzugefügt	05
07	Reworking of the layout and adding CE marking, SRN, Intended purpose	06

## Annex 1

Product	REF	Intended Purpose	Basic UDI-DI	UDI-DI
<p><b>ALEX<sup>2</sup> Allergy Xplorer, consisting of</b></p> <ul style="list-style-type: none"> <li>20 x ALEX<sup>2</sup> Cartridges</li> <li>2 x 50 mL ALEX<sup>2</sup> Washing Solution</li> <li>1 x 9 mL ALEX<sup>2</sup> Sample Diluent</li> <li>1 x 11 mL ALEX<sup>2</sup> Detection Antibody</li> <li>1 x 11 mL ALEX<sup>2</sup> Substrate Solution</li> <li>1 x 2.4 mL ALEX<sup>2</sup> Stop Solution</li> </ul>	REF 02-2001-01	<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><b>ALEX<sup>2</sup> Allergy Xplorer, consisting of</b></p> <ul style="list-style-type: none"> <li>50 x ALEX<sup>2</sup> Cartridges</li> <li>1 x 250 mL ALEX<sup>2</sup> Washing Solution 4x conc</li> <li>1 x 30 mL ALEX<sup>2</sup> Sample Diluent</li> <li>1 x 30 mL ALEX<sup>2</sup> Detection Antibody</li> <li>1 x 30 mL ALEX<sup>2</sup> Substrate Solution</li> <li>1 x 10 mL ALEX<sup>2</sup> Stop Solution</li> </ul>	REF 02-5001-01		91201229202JQ	9120122920251