

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 in vitro diagnostic medical devices described above are in conformity with the following legislation: Directive 98/79/EC



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Dr. Christian Harwanegg, CEO of MADx

Document Change History

Version	Description	Replaces
1.0	First compilation	Former version
2.0	Reworking of the layout and adding CE marking, SRN, Intended purpose	1.0
3.0	Addition of FOX variant (250 tests)	2.0

Annex 1

Product	REF	Intended Purpose	Basic UDI-DI	UDI-DI
FOX Food Xplorer, consisting of 50 x FOX Cartridges 1 x 250 mL FOX Washing Solution 4x conc 1 x 30 mL FOX Sample Diluent 1 x 30 mL FOX Detection Antibody 1 x 30 mL FOX Substrate Solution 1 x 10 mL FOX Stop Solution	80-5001-01	<p>The Food Xplorer (FOX) is a semi-quantitative in-vitro diagnostic test for the determination of specific immunoglobulin G (IgG) against 286 food antigens. The Food Xplorer is suitable for use with serum or plasma. FOX can be used to support dietary clarification and to monitor dietary compliance. Furthermore, FOX can be used in case of reasonable suspicion of immunologically caused food intolerance. Before starting a diet based on FOX results, it is important to discuss the results with a physician or a dietician. The processing of FOX should always be carried out by professionally trained personnel and/or medical professionals.</p>	91201229202JQ	9120122928059
FOX Food Xplorer, consisting of 250 x FOX Cartridges 5 x 250 mL FOX Washing Solution 4x conc 5 x 30 mL FOX Sample Diluent 5 x 30 mL FOX Detection Antibody 5 x 30 mL FOX Substrate Solution 5 x 10 mL FOX Stop Solution	80-0001-01			9120122928004