

## 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

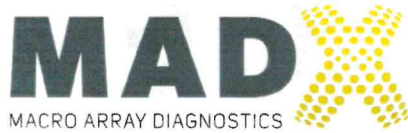
**Conformity Assessment:** In accordance with Reg. (EU) 2017/746 Article 48 (10) and Annex II+III

**Notified Body:** N/A

**Notified Body Number:** N/A

**Certificates Issued by Notified Body:** N/A

**Applicable Legislation:** The in vitro diagnostic medical devices described above are in conformity with the following legislations:  
Regulation (EU) 2017/746



Vienna, Austria  
20.05.2026

**Dr. Christian Harwanegg,**  
Chief Executive Officer,  
MacroArray Diagnostics GmbH



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#### Document Change History

Version	Description	Replaces
1.0	Initial creation and reworking of the document for the IVDR, according to the ÄA – 24042020.	-
2.0	German translation, SRN added.	1.0
3.0	Applicable Legislation, CE Marking added, translation moved to another document.	2.0
4.0	No changes in the content of the document, but the document is now based on an officially approved template.	3.0



# Annex 1

Product	REF	Risk Classification & Rule	Intended Purpose	Basic UDI-DI	UDI-DI
Washing Solution 4x conc.	00-5003-01	Class A, Rule 5a	The Washing Solution is an accessory for ALEX technology-based assays. The IVD medical product is used as indicated in the respective Instruction for Use and is used by trained laboratory personnel and medical professionals in a medical laboratory.	9120122925036H	9120122925034