



## DECLARATION OF CONFORMITY

Manufacturer: MacroArray Diagnostics (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: ConfigXplorer  
(REF 30-0100-01, Basic UDI-DI: 91201229230JV, UDI-DI (GTIN): 9120122923009)

Intended Purpose: The ConfigXplorer is an accessory to support the MADx hardware systems. The IVD medical product configures the MADx hardware systems for the ideal camera settings and is used by trained laboratory personnel and medical professionals in a medical laboratory.

Risk Classification & Rule: Class A, Rule 5a

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

Applicable Legislation: The vitro diagnostic medical devices described above are in conformity with the following legislations: Regulation (EU) 2017/746, Regulation (EC) 765/2008



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Dr. Christian Harwanegg, CEO of MADx

### Document Change History

Version	Description	Replaces
01	Complete reworking for IVDR according to AA_24042020 Umstellung auf IVDR	Former version
02	German translation; SRN added	01
03	Applicable Legislation, CE marking added, translation moved to other document	02