

## IZJAVA O SKLADNOSTI

**Proizvajalec**

MacroArray Diagnostics GmbH (MADx)  
Lemböckgasse 59, Top 4  
1230 Dunaj, Avstrija

**SRN**

AT-MF-000030541

Izjavljamo, da je ta izjava EU o skladnosti izdana na našo izključno odgovornost in da spodaj navedeni in vitro diagnostični medicinski pripomočki izpolnjujejo vse določbe Uredbe (EU) 2017/746 in veljavne zakonodaje, ki se uporablja zanje.

**Proizvodi**

Glej Prilogo 1

**Predvideni namen**

Glej Prilogo 1

**Ocenjevanje skladnosti**

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

**Priglašeni organ**

N/A

**Številka priglašene organa**

N/A

**Certifikati, ki jih izda  
priglašeni organ**

N/A

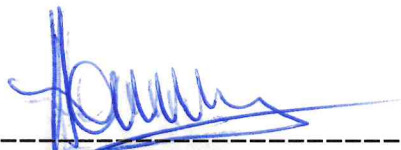
**Veljavna zakonodaja**

Zgoraj opisani in vitro diagnostični medicinski pripomočki so v skladu z naslednjimi zakonodajami:

Uredbo (EU) 2017/746

Dunaj, Avstrija

20.05.2026



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



Macro Array Diagnostics GmbH  
Lemböckgasse 59 / Top 4 - 1230 Wien  
M: office@macroarraydx.com • P: +43 (0)1865 25 73  
UID: ATU70451058 • FN 448974 g  
www.macroarraydx.com

**Zgodovina sprememb dokumentov:**

Različica	Opis	Nadomešča
1.0	Initial compilation of the document in Slovenian language, according to the following version of the document in English: 17-DOC-EN-04.	-



# Priloga 1

Proizvod	REF	Razvrščanje tveganj in pravila	Predvideni namen	Basic UDI-DI	UDI-DI
MAX 9k	17-0000-01	Class A, Rule 5b	<p>The MAX 9k is an instrument and intended as accessory to ALEX technology-based products. The IVD medical product automatically processes up to 10 ALEX technology-based arrays in one run and acquires pictures of those. It is used by trained laboratory personnel and medical professionals in a medical laboratory.*</p> <p>*As there is no officially reviewed and approved version of the Slovenian Intended Purpose, we are using the English version here and we deem it acceptable.</p>	91201229217K5	9120122921708