

## IZJAVA O SKLADNOSTI

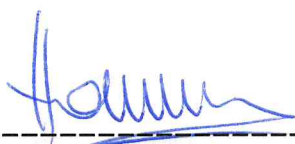
<b>Proizvajalec</b>	MacroArray Diagnostics GmbH (MADx) Lemböckgasse 59, Top 4 1230 Dunaj, Avstrija
<b>SRN</b>	AT-MF-000030541

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.

<b>Proizvodi</b>	Glej Prilogo 1
<b>Predvideni namen</b>	Glej Prilogo 1
<b>Ocenjevanje skladnosti</b>	In accordance with Reg. (EU) 2017/746 Article 48 (10) and Annex II+III
<b>Priglašeni organ</b>	N/A
<b>Številka priglašene organa</b>	N/A
<b>Certifikati, ki jih izda priglašeni organ</b>	N/A
<b>Veljavna zakonodaja</b>	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)1 865 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: 16-DOC-EN-05.	-



# Priloga 1

Proizvod	REF	Razvrščanje tveganj in pravila	Predvideni namen	Basic UDI-DI	UDI-DI
MAX 45k	16-0000-01	Class A, Rule 5b	<p>The MAX 45k is an instrument and intended as accessory to ALEX technology-based products. The IVD medical product automatically processes ALEX technology-based arrays and acquires pictures of those. The product is used by trained laboratory personnel and medical professionals in a medical laboratory.*</p> <p>*As there is no officially reviewed and approved translation of the Intended Purpose in Slovenian, we are putting the English version of it in the Annex and we deem it acceptable.</p>	91201229216K3	9120122921609