

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

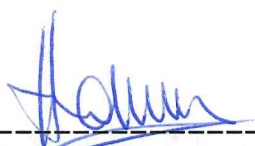
Številka priglašene organa N/A

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



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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: 11-DOC-EN-05.	-



Priloga 1

Proizvod	REF	Razvrščanje tveganj in pravila	Predvideni namen	Basic UDI-DI	UDI-DI
ImageXplorer	11-0000-01	Class A, Rule 5b	<p>The ImageXplorer is an instrument and intended as accessory to ALEX technology-based products.</p> <p>The IVD medical product acquires pictures of the ALEX technology-based arrays and 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>	91201229211JR	9120122921104