

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



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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: 00-07-DOC-EN-04.	-

Priloga 1

Proizvod	REF	Razvrščanje tveganj in pravila	Predvideni namen	Basic UDI-DI	UDI-DI
Stop Solution	00-5007-01	Class A, Rule 5a	<p>The Stop Solution is an accessory to ALEX technology-based assays. The IVD medical product is used as indicated in the respective Instructions for Use and 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>	9120122925076R	9120122925072