

## 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>	Annex IX, chapter I + III
<b>Priglašeni organ</b>	QMD Services GmbH
<b>Številka priglašenega organa</b>	2962
<b>Certifikati, ki jih izda priglašeni organ</b>	EU QMS certificate: IQMS/00003/0 v002
<b>Veljavna zakonodaja</b>	Zgoraj opisani in vitro diagnostični medicinski pripomočki so v skladu z naslednjimi zakonodajami: Uredbo (EU) 2017/746 Uporabljeni so bili naslednji standardi: EN ISO 9001:2015, EN ISO 13485:2016 + AC:2018 + A11:2021, EN 13612:2002, EN 13641:2002, EN ISO 14971:2019, EN ISO 15223-1:2022-02, EN ISO 17511:2020, EN ISO 18113-1:2022, EN ISO 18113-2:2022, EN ISO 18113-3:2022, EN ISO 20417:2021, EN ISO 20916:2021, EN ISO 23640:2015, EN 61010-2-101:2017, EN 61326-2-6:2013, EN 62304:2006, IEC 62304:2006 + A1:2015, IEC 62366-1:2015 + COR1:2016 + A1:2020

Dunaj, Avstrija

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**Zgodovina sprememb dokumentov:**

Različica	Opis	Nadomešča
1.0	Initial compilation in Slovenian language according to the following version of the English document: 06-DOC-EN-02.	-



# Priloga 1

Proizvod	REF	Razvrščanje tveganj in pravila	Predvideni namen	Basic UDI-DI	UDI-DI
ALEX Air consisting of: 50x ALEX Air Cartridges 1 x 250 mL Washing Solution 4x conc 1 x 30 mL ALEX Air Sample Diluent 1 x 30 mL ALEX Air Detection Antibody 1 x 30 mL ALEX Air Substrate Solution 1 x 10 mL Stop Solution	06-5001-01	Class C, Rule 3e	<p>The ALEX Air test system is a quantitative in vitro diagnostic test for the measurement of 59 allergen specific IgE (sIgE) of inhalative allergens and a semi-quantitative in vitro diagnostic test for the measurement of total IgE (tIgE) in human serum or plasma (exception EDTA plasma).</p> <p>It is to be used by clinical chemistry laboratories, trained laboratory personnel and medical professionals for the purpose of supporting the clinical diagnosis of IgE mediated diseases, in conjunction with other clinical findings or diagnostic test results. The test is intended for MAX 45k and MAX 9k only.*</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>	91201229206JY	9120122920657