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MADX
MACRO ARRAY DIAGNOSTICS

CE 2962

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	Annex IX, chapter I + III
Priglašeni organ	QMD Services GmbH
Številka priglašenega organa	2962
Certifikati, ki jih izda priglašeni organ	EN ISO 13485: registration no. M-00266/0 EU QMS certificate: IQMS/00003/0 v002
Veljavna zakonodaja	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

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20.05.2026

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

Zgodovina sprememb dokumentov:

Različica	Opis	Nadomešča
1.0	Initial compilation in Slovenian language according to the following English version of the document: 02-DOC-EN-03.	-

Priloga 1

Proizvod	REF	Razvrščanje tveganj in pravila	Predvideni namen	Basic UDI-DI	UDI-DI
ALEX² Allergy Xplorer *consisting of:* 20x ALEX² Cartridges 2 x 50 mL Washing Solution 1 x 9 mL ALEX² Sample Diluent 1 x 11 mL ALEX² Detection Antibody 1 x 11 mL ALEX² Substrate Solution 1 x 2.4 mL Stop Solution	02-2001-01	Class C, Rule 3e	The ALEX² Allergy Xplorer is a test kit used for in-vitro examination of human serum or plasma (exception EDTA-plasma) to provide information to aid the diagnosis of patients suffering from IgE-mediated diseases in conjunction with other clinical findings or diagnostic test results. The IVD medical device detects allergen-specific IgE (sIgE) quantitatively and total IgE (tIgE) semi-quantitatively. The product is used by trained laboratory personnel and medical professionals in a medical laboratory.* *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.	91201229202JQ	9120122920220
ALEX² Allergy Xplorer *consisting of:* 50x ALEX² Cartridges 1 x 250 mL Washing Solution 4x conc 1 x 30 mL ALEX² Sample Diluent 1 x 30 mL ALEX² Detection Antibody 1 x 30 mL ALEX² Substrate Solution 1 x 10 mL Stop Solution	02-5001-01				9120122920251