www.madx.com

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	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

www.madx.com

MADX
MACRO ARRAY DIAGNOSTICS

CE 2962

Dunaj, Avstrija

20.05.2026

MADX
MACRO ARRAY DIAGNOSTICS
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

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

Zgodovina sprememb dokumentov:

Različica	Opis	Nadomešča
1.0	Initial compilation in Slovenian language, based on the following document in English: 07-DOC-EN-02.	-

Priloga 1

Proizvod	REF	Razvrščanje tveganj in pravila	Predvideni namen	Basic UDI-DI	UDI-DI
ALEX Food *consisting of:* 50x ALEX Food Cartridges 1 x 250 mL Washing Solution 4x conc 1 x 30 mL ALEX Food Sample Diluent 1 x 30 mL ALEX Food Detection Antibody 1 x 30 mL ALEX Food Substrate Solution 1 x 10 mL Stop Solution	07-5001-01	Class C, Rule 3e	The ALEX Food test system is a quantitative in vitro diagnostic test for the measurement of 59 allergen specific IgE (sIgE) food allergens and a semi-quantitative in vitro diagnostic test for the measurement of total IgE (tIgE) in human serum or plasma (exception EDTA-plasma). 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.* *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.	91201229207K2	9120122920756