

IZJAVA O SKLADNOSTI

Proizvajalec

MacroArray Diagnostics GmbH (MADx)
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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 priglašene 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

Dunaj, Avstrija

20.05.2026



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Zgodovina sprememb dokumentov:

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



Priloga 1

Proizvod	REF	Razvrščanje tveganj in pravila	Predvideni namen	Basic UDI-DI	UDI-DI
ALEX ³ Allergy Xplorer consisting of: 20x ALEX ³ Cartridges 2 x 50 mL Washing Solution 1 x 9 mL ALEX ³ Sample Diluent 1 x 11 mL ALEX ³ Detection Antibody 1 x 11 mL ALEX ³ Substrate Solution 1 x 2.4 mL Stop Solution	03-2001-01	Class C, Rule 3e	ALEX ³ 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) quantitatively in the range from 2 - 1000 kU/l (semi-quantitative 1001-2500 kU/l). The product is used by trained laboratory personnel and medical professionals in a medical laboratory.*	9120122920329	9120122920329
ALEX ³ Allergy Xplorer consisting of: 50x ALEX ³ Cartridges 1 x 250 mL Washing Solution 4x conc 1 x 30 mL ALEX ³ Sample Diluent 1 x 30 mL ALEX ³ Detection Antibody 1 x 30 mL ALEX ³ Substrate Solution 1 x 10 mL Stop Solution	03-5001-01		*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.		9120122920350