

KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE

Produkt / Product	ALEX Allergy Explorer (REF 01-2001-01)
Bestehend aus /containing	ALEX Cartridge ALEX Washing Solution ALEX Sample Diluent ALEX Detection Antibody ALEX Substrate Solution ALEX Stop Solution
Klasse / class	Allgemeine Klasse – sonstiges Produkt / Other Device
Manufacturer	Macro Array Diagnostics GmbH Gutheil Schoder Gasse 17 AT - 1230 Wien

Wir erklären in alleiniger Verantwortung, dass das oben genannte Medizinprodukt für die In-vitro-Diagnostik allen Anforderungen der Richtlinie über In-vitro-Diagnostika 98/79/EG entspricht, die anwendbar sind.

We declare under our sole responsibility that the above mentioned in vitro diagnostic medical device meets all the provisions of the directive on in vitro diagnostic medical devices 98/79/EC which apply to it.

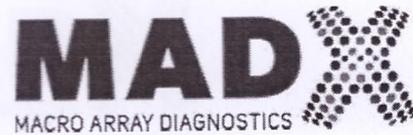
QM Zertifikat / QM certificate	ISO 9001:2015 gültig bis / valid until 08.08.2020 ISO 13485:2016 gültig bis / valid until 08.08.2020
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Konformitätserklärung	gültig bis 30.09.2020
Declaration of conformity	valid until 30.09.2020

Wien, am 02.10.2017



Christian Harwanegg
Geschäftsleitung / CEO MADx



ATITIKTIES DEKLARACIJA / DECLARATION DE CONFORMITE

Gaminys / Product	ALEX Allergy Explorer (REF 01-2001-01)
Susideda iš /containing	ALEX Cartridge ALEX Washing Solution ALEX Sample Diluent ALEX Detection Antibody ALEX Substrate Solution ALEX Stop Solution
Klasė / class	Bendroji klasė – kitas gaminys / Other Device
Gamintojas	Macro Array Diagnostics GmbH Gutheil Schoder Gasse 17 AT - 1230 Viena

Visiškai atsakingai pareiškiame, kad viršuje nurodytas medicininis gaminys, skirtas in vitro diagnostikai, atitinka visus taikomus reikalavimus, kurie yra numatyti Direktyvoje dėl in vitro diagnostikos medicinos prietaisų 98/79/EB.

We declare under our sole responsibility that the above mentioned in vitro diagnostic medical device meets all the provisions of the directive on in vitro diagnostic medical devices 98/79/EC which apply to it.

QM sertifikatas / QM certificate	ISO 9001:2015 galioja iki / valid until 2020-08-08 ISO 13485:2016 galioja iki / valid until 2020-08-08
Atitikties deklaracija	galioja iki 2020-09-30
Declaration of conformity	valid until 30.09.2020

Viena, 2017-10-02

A handwritten signature in black ink, appearing to read 'Christian Harwanegg', written over a horizontal dashed line.

Christian Harwanegg
Vadovybė / CEO MADx



Translation Bureau
"Lingua"

[Handwritten signature]

Susiūta, sunumeruota ir
antspaudu patvirtinta
.....&.....lapai (u)