

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 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

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 version of the document in English: 22-DOC-EN-03.	-



Priloga 1

Proizvod	REF	Razvrščanje tveganj in pravila	Predvideni namen	Basic UDI-DI	UDI-DI
RAPTOR SERVER Analysis Software	22-0000-01	Class C, implementing rule 1.4	<p>The RAPTOR SERVER Analysis Software drives and influences MADx processing systems in combination with ALEX technology-based products. The software analyzes the output from ALEX technology-based arrays and is used by trained laboratory personnel and medical professionals in a medical laboratory.</p> <p>*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.</p>	91201229222JW	9120122922200