

## KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

Produkt / Product	ImageExplorer (REF 11-0000-01)
Klasse / class	Allgemeine Klasse – sonstiges Produkt / Other Device
Manufacturer	Macro Array Diagnostics GmbH Gutheil Schoder Gasse 17 AT - 1230 Wien

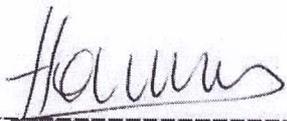
Wir erklären in alleiniger Verantwortung, dass das oben genannte Medizinprodukt für die In-vitro-Diagnostik allen Anforderungen der Richtlinie über In-vitro-Diagnostika 98/79/EG entspricht, die anwendbar sind.

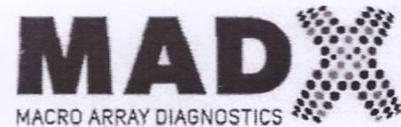
We declare under our sole responsibility that the above mentioned in vitro diagnostic medical device meets all the provisions of the directive on in vitro diagnostic medical devices 98/79/EC which apply to it.

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 Declaration of conformity	gültig bis 30.09.2020 valid until 30.09.2020
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Wien, am 30.08.2017

  
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Christian Harwanegg  
Geschäftsleitung / CEO MADx



## ATITIKTIES DEKLARACIJA / DECLARATION OF CONFORMITY

Gaminys / Product	ImageXpforer (REF 11-0000-01)
Klasė / class	Bendroji klasė – kitas gaminys / Other Device
Gamintojas	Macro Arrag 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
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Atitikties deklaracija	galioja iki 2020-09-30
Declaration of conformity	valid until 30.09.2020

Viena, 2017-08-30

Christian Harwanegg  
Vadovybė / CEO MADx



Translation Bureau  
"System Lingua"

*[Handwritten signature]*

Susiūta, sunumeruota ir  
antspaudu patvirtinta  
.....*2*.....lapai (u)