

## EC Declaration of Conformity

for In Vitro Diagnostic Medical Devices  
according to Annex III of the 98/79/EC IVD Directive

**BioMaxima S.A.**

Vetterów 5, 20-277 Lublin, Poland

We hereby declare under our sole responsibility that the products listed in the attached Product List, classified as “all other IVD Medical Devices” according to Article 9 rules, conform to the relevant provisions of the EC Council Directive 98/79/EC and are in accordance with Annex III of the IVDD, as implemented by the European Union's Medical Devices Regulations.

The following standards have been applied:

EN ISO 9001:2008, EN ISO 13485:2003, EN ISO 14971:2012, EN ISO 61010-2-101:2002, EN ISO 18113-2:2011, EN ISO 13612:2002, EN ISO 14971:2012 and internal technical specifications of BioMaxima S.A.

Signed on behalf of BioMaxima S.A.:

Name: Krzysztof Pawluk

Function: Business Development Director

Place and date of issue:

Lublin, 2015-04-03

Dyrektor ds. Produktów i Rozwoju  
BioMaxima S.A.  
*Krzysztof Pawluk*  
**Krzysztof Pawluk**

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This is an attachment to EC Declaration of Conformity issued by BioMaxima S.A.  
on the 3 April 2015.

Product	Catalog number
BM Diluent	1-110-0020
BM Cleaner	1-112-0001
BM Lizat	1-111-0001
BM External cleaner	1-114-0100
BM Diluent S	1-DS-0020
BM Diluent S	1-DS-0010
BM Lizat S	1-LS-0001
BM Sol S	1-SS-0001
BM Sol S	1-SS-0005
BM Pack Smart	1-PS-0100
BM Pack Smart	1-PS-0300
BM Pack Smart	1-PS-1000
BM 3 Diff Control Low	1-116-0004
BM 3 Diff Control Normal	1-117-0004
BM 3 Diff Control High	1-118-0004
BM Diluent M	1-110-0021
BM Lizat M	1-111-0002
BM Cleaner M	1-112-0002
BM External cleaner E	1-115-0100
Pack BM ISE Na/K/Cl/Ca/pH	1-654-1000
BM ISE Daily cleaning solution	1-669-0100
BM ISE Ref. filling solution	1-667-0100
BM ISE Na/Cl/pH filling solution	1-664-0100
BM ISE K filling solution	1-663-0100
BM ISE Weekly filling solution	1-662-0100
BM ISE Ca filling solution	1-665-0100
BM ISE QC control solution	1-661-0100
BM ISE QC + Ca control solution	1-670-0100
BM URI 10	1-550-0100
BM URI 11	1-551-0100
BM URI 10C	1-552-0100
BM URI 10Q	1-555-0016
BM URI 11Q	1-556-0024

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**EC Declaration of Conformity**  
**Product List**  
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<b>Product</b>	<b>Catalog number</b>
Giardia strip	1-325-P020
Giardia cassette	1-325-K020
Giardia control	1-325-K010
Multi Drug Test cassette	1-336-K020
Helicobacter Pylori strip	1-301-P050
Helicobacter Pylori cassette	1-301-K020
Helicobacter Pylori Ag cassette	1-302-K020
Pregnancy test strip	1-307-P050
Pregnancy test cassette	1-307-K040
Cocaine strips	1-313-P050
Cocaine cassette	1-313-K040
Barbiturates strips	1-314-P050
Barbiturates cassette	1-314-K040
Benzodiazepines strips	1-312-P050
Benzodiazepines cassette	1-312-K040
Opiates strips	1-310-P050
Opiates cassette	1-310-K040
Marihuana strips	1-311-P050
Marihuana cassette	1-311-K040
Amphetamine strips	1-309-P050
Amphetamine cassette	1-309-K040
Syphilis strips	1-308-P050
Syphilis cassette	1-308-K040
FOB cassette	1-300-K020
FOB cassette + control	1-300-KK20
ASO Latex 100	1-901-1001
ASO Latex 100 with controls	1-901-1002
CRP Latex 100	1-906-1001
CRP Latex 100 with controls	1-906-1002
RF Latex 100	1-911-1001
RF Latex 100 with controls	1-911-1002
RPR Carbon 100	1-916-1001
RPR Carbon 100 with controls	1-916-1002
RPR Carbon 250 with controls	1-916-2505

Signed on behalf of BioMaxima S.A.:

Name: Krzysztof Pawluł

Function: Business Development Director

Place and date of issue:

Lublin, 2015-04-03

dyrektor ds. Produktów i Rozwoju

BioMaxima S.A.

*Krzysztof Pawluł*  
**Krzysztof Pawluł**