BioMaxima

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 13612:2002, EN 13640:2002, EN ISO 14971:2012, EN ISO 18113-1/2:2011and internal technical specifications of BioMaxima S.A.

Signed on behalf of BioMaxima S.A.:

Name: Krzysztof Szlachetka

Function: V-ce President

Place and date of issue:

Lublin, 2013-12-11

BioMaxima S.A.
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Zarejestrowano pod nr KRS 0000313349
w Sądzie Rejonowym Lublin-Wschód w Lublinie
z siedzibą w Świdniku, VI Wydział Gospodarczy
Kapitał Zakładowy 3.040.000,00 zł
NIP 946-23-60-625
REGON 432519331

BioMaxima

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Product List
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This is an attachment to EC Declaration of Conformity issued by BioMaxima S.A. on 11 December 2013.

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 M	**1-110-0021**
BM Lizat M	**1-111-0002**
BM Cleaner M	**1-112-0002**
BM External Cleaner E	**1-115-0100**
BM 3-Diff Control LNH	**1-115-0018**
BM 3-Diff Control Normal	**1-116-0018**
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**

Signed on behalf of BioMaxima S.A.:

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Function: V-ce President

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