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: Henryk Lewczuk

Function: President

Place and date of issue:

Lublin, 2014-09-06

Prezes Zarządu
BioMaxima S.A.
Henryk Lewczuk

BioMaxima S.A.
20-277 Lublin, ul. Vetterów 5
tel. 81 745 51 40, fax 81 744 29 15
NIP 946-23-60-625

BioMaxima

CERTYFIKACJA SYSTEMU JAKOŚCI ISO 9001 = ISO 13485 DNV

EC Declaration of Conformity
Product List
page 1/1

This is an attachment to EC Declaration of Conformity issued by BioMaxima S.A. on 06 September 2014.

Product	Catalog Number
Pack BM ISE Na/K/Cl/Ca/pH	1-654-1000
BM ISE Daily cleaning solution	1-669-0100
BM ISE Ref. filing solution	1-667-0100
BM ISE Na/Cl/pH filing solution	1-664-0100
BM ISE K filing solution	1-663-0100
BM ISE Cleaning solution	1-662-0100
BM ISE Ca filing solution	1-665-0100
BM ISE QC control solution	1-661-0100
BM ISE QC + Ca control solution	1-670-0100

Prezes Zarządu
BioMaxima S.A.
Henryk Lewczuk

BioMaxima S.A.
20-277 Lublin, ul. Vetterów 5
tel. 81 745 51 40, fax 81 744 29 15
NIP 946-23-60-625