

Annex III

Declaration of CE-Conformity

The products (see Annex II)

meet the essential requirements of the directive 98/79/EG of 27. October 1998 on in vitro diagnostic medical devices.

The technical documentation according to this directive may be reviewed at the manufacturer

BioCheck, Inc.

The manufacturer will provide ETG EOOD with a short documentation, consisting of the following items:

- **Instructions for Use**
- **Material Safety Data Sheets**
- **Summary of the Evaluation Data**
- **QC-Certificate with each Lot**
- **Risk analysis (see table enclosed)**
- **Information of any finding which could lead to a serious risk for the user, patient or other person.**
- **any important change of the product or documentation**

In case of an incident with the product or in case of an official inquiry, the manufacturer will provide ETG EOOD with all other requested documentation without delay.

Responsible to carry out these duties at the manufacturer's office is Mrs. Anna Pao.

Date: 12/07/07

Anna Pao
Signature responsible person

ANNEX I

BioCheck, Inc. PRODUCT LISTING:

Product Name	Original Supplier's Cat.-No.
TSH EIA Kit	BC-1001
U-TSH EIA Kit	BC-1003
T3 EIA Kit	BC-1005
Free-T3 EIA Kit	BC-1006
T4 EIA Kit	BC-1007
Free-T4 EIA Kit	BC-1008
AFP EIA Kit	BC-1009
CEA EIA Kit	BC-1011
CA125 EIA Kit	BC-1013
CA15-3 EIA Kit	BC-1015
CA19-9 EIA Kit	BC-1017
PSA EIA Kit	BC-1019
Free-PSA EIA Kit (For research use only)	BC-1021
Free- β -HCG EIA Kit	BC-1023
Ferritin EIA Kit	BC-1025
hCG EIA Kit	BC-1027
FSH EIA Kit	BC-1029
LH EIA Kit	BC-1031
HGH EIA Kit	BC-1033
IgE EIA Kit	BC-1035
Prolactin EIA Kit	BC-1037
Visual hCG EIA Kit	BC-1045
<i>H. pylori</i> IgG EIA Kit	BC-1051
<i>H. pylori</i> IgG Quantitative EIA Kit	BC-1051
<i>H. pylori</i> IgM EIA Kit	BC-1053
Rubella IgG EIA Kit (For research use only)	BC-1081
Rubella IgM EIA Kit (For research use only)	BC-1083
Toxo IgG EIA Kit (For research use only)	BC-1085
Toxo IgM EIA Kit (For research use only)	BC-1087
CMV IgG EIA Kit	BC-1089
CMV IgM EIA Kit	BC-1091
HSV I IgG EIA Kit	BC-1093
HSV I IgM EIA Kit	BC-1095
HSV II IgG EIA Kit	BC-1097
HSV II IgM EIA Kit	BC-1099
Troponin I EIA Kit	BC-1105
Myoglobin EIA Kit	BC-1117
Hs CRP EIA Kit	BC-1119