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DECLARATION OF CONFORMITY

MANUFACTURER NAME: **"BIOPROMIN" LTD**

MANUFACTURER ADDRESS: **KHALTURINA STR, 50, APT.2, KHARKIV 61038, UKRAINE**

MANUFACTURER FACILITY ADDRESS: **KHALTURINA STR, 50, APT.2, KHARKIV 61038, UKRAINE**

EUROPEAN REPRESENTATIVE: MEDICAL DEVICES S.R.O.

NAME OF DEVICE:

NONINVASIVE HEMOGRAM ANALYZER (AMP)

CLASSIFICATION: **Class IIa**

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED:

EN ISO 9001:2001 EN ISO 13485:2004 EN ISO 60601-1:1997 EN ISO 60601-1-1:2001 EN ISO 60601-1-4:1999 EN 60601-1-2-:2002 EN ISO 14971:2000 EN 980:2003

NOTIFIED BODY:

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