

EC CERTIFICATE
Production Quality Assurance
Directive 93/42/EEC on Medical devices, Annex V

No. 5-721-500-1208

**National Institute for Quality- and Organizational Development
in Healthcare and Medicines**

Directorate of Device Testing and Clinical Engineering (EMKI)

certifies that the manufacturer:

«BIOPROMIN» Ltd.
Khalturina str. 50
61038 Kharkiv, Ukraine

with authorized representative in EU:

Medical Devices s.r.o.
Nemocnica16
99001 Velky Krtis, Slovakia

for the product:

Low intensity microwave-therapy device (BIOL)

applies a quality which meets the requirements of Directive 93/42/EEC on Medical devices,
Annex V.

Registry number of the related audit report: **42-075-2007**

This Certificate is valid until **2017-07-31** supposed that the results of the regular yearly surveillance
audits are satisfactory.

Issued by EMKI as a Notified Body with identification number **1011**.

Budapest, 2012-08-01




General Director


Certification Office



EMKI 0800

The authenticity and validity of the certificate is verifiable at EMKI.

Gyógyszerészeti és Egészségügyi Minőség- és Szervezetfejlesztési Intézet
National Institute for Quality- and Organizational Development in Healthcare and Medicines
Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering

EMKI

H-1125 Budapest, Diós árok 3.
Tel.: +36 1 356 1522 Fax: +36 1 375 7253

Internet: www.gycmszi.hu