

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

EMKI certifies that the manufacturer

Number of certificate: 5-628-500-0911

Research and Production Complex "BIOPROMIN" Ltd.
30 "a" Seljanskaja Str., apt. 32, Kharkiv, 61157, Ukraine
50 Khalturina Str., apt. 2, Kharkiv, 61038, Ukraine

with authorized representative in EU

Medical Devices s.r.o.
Nemocnica 16, Velky Krtis 99001, Slovakia

for the products

Noninvasive hemogram analyzer (AMP)
Low intensity microwave-therapy device (BIOL)

applies a quality system in the manufacturing process which ensures that the products are manufactured in conformity with the technical documentation (referred to in Annex VII and kept by the manufacturer)

Number of the audit report on the assessment: 42-075-2007

Provided the yearly surveillance is carried out successfully this certificate is valid until:

2012-06-20

Issued by EMKI a Notified Body for the Council Directive 93/42/EEC with identification number
1011.

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Budapest, 2010-07-14


General Director


Certification Office





EMKI 0097

The validity of the certificate is verifiable at the Certification Office of the Institute for Healthcare Quality Improvement and Hospital Engineering.

Egészségügyi Minőségfejlesztési és Kórháztechnikai Intézet
Institute for Healthcare Quality Improvement and Hospital Engineering

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