EC CERTIFICATE

Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V

No. 5-732-500-1303

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

Directorate of Device Testing and Clinical Engineering (EMKI)

certifies that the manufacturer:

Research and Production Company "DINAMIKA" Ltd.
16 Moskovskoe Street
196158 Saint Petersburg
Russia

with authorized representative in EU:

Medical Devices s.r.o.
Nemocnicna 16
99001Velky Krtis
Slovakia

for the product / product category:

HRV monitor
Product names: "Dinamika", "Cardiaum", "Alfa", "Vitaspect", "Altair"

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

Registry number of the related audit report: **42-011-2008**

This Certificate is valid until **2018-03-10** supposed that the results of the regular yearly surveillance audits are satisfactory.

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

Budapest, 2013-03-11

General Director | Certification Office | EMKI 0899

The authenticity and validity of the certificate are 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
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