

EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-850-200-1806

The Directorate of Device Testing and Clinical Engineering (EMKI)

certifies that the manufacturer:

Labtech Kft.
Vág utca 4.
4031 Debrecen
Hungary

for the products / product category:

ECG systems with Cardiospy softwer for non-invasive cardiology diagnostics

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report: **42-3482-2018**

This certificate is valid until **2023-06-15** supposed that the results of the regular yearly surveillance audits are satisfactory.

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

This certificate is valid only with the attachment.

Budapest, 2018-06-16



Head of EMKI



EMKI 2028

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