

EC CERTIFICATE
Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-850-200-1806

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.
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: **NE/1043/2020**

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


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

This certificate is valid only with the attachment.

Issue: 2

First issued by the Directorate of Device Testing and Clinical Engineering (EMKI) on 16 June 2018.

Budapest, 2020-07-28


László Imre
Managing Director



EMKI 2517

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.
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ATTACHMENT TO EC CERTIFICATE

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Additional information for Certificate No. 5-850-200-1806

The certificate is valid for the following IIa class products / models:

ECG systems with Cardiospy software for non-invasive cardiology diagnostics

EC type Holter systems

with “Cardiospy” software

including EC-2H, EC-3H, EC-12H, EC-ABP, EC-3H/ABP models

EC type resting and stress test ECG systems

with “Cardiospy” software

including EC-12R, EC-12RM, EC-12S, EC-12R/S, EC-3RT, EC-12RT, EC-12LT models

Issue: 2

Date: 2020-07-28

First issued: 2018-06-16


László Imre
Managing Director



EMKI