

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.
neoEMKI National Medical Device Conformity Assessment and Certification LLC.

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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