

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

No. 5-877-200-2001

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.
certifies that the manufacturer:

Pentavox Kft.
Dugonics u. 11.
1043 Budapest
Hungary

for the product / product category:

Ambulant cardiocograph with passive sensor: Fetaphon Home Monitor

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/1007/2020**

This certificate is valid until **2024-05-26** supposed that the results of the regular yearly surveillance audits are satisfactory.

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

Issue: 2

First issued by the Directorate of Device Testing and Clinical Engineering (EMKI) on 28 January 2020.

Budapest, 2020-09-25



László Imre
Managing Director



EMKI 2569

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