

Declaration of Conformity

Prohlášení o shodě

We declare conformity according to EC-Directive 93/42/EEC concerning medical devices

Manufacturer: SEIVA s. r. o., Schnirchova 8/1356, 170 00 Praha 7

Product: Electrocardiograph

Type: SEIVA EKG Praktik

Model: Praktik – resting ECG
JetCard – resting ECG
Ergolog – stress test ECG

Intended use: The device is intended to capture electrocardiograms from the surface of a human body for diagnostic purposes. It is intended for non-invasive, non-sterile, reusable and transient use.

Classification: IIa

To comply to the conformity the following standards were used:

EN 60601-1	Medical Electrical Equipment - Part 1: General requirements for safety
EN 60601-2-25	Medical Electrical Equipment - Part 2: Particular Requirements for safety of Electrocardiographs
EN 60601-1-2	Medical electrical equipment - Part 1: General requirements for safety: 2. Collateral standard: Electromagnetic compatibility; Requirements and tests
EN 55011	Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurement
EN 61000-4-2	Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 2: Electrostatic discharge immunity test - Basic EMC
Publication	
EN 61000-4-3	Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 3: Radiated, radio-frequency, electromagnetic field immunity test
EN 61000-4-4	Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 4: Electrical fast transients/burst immunity test - Basic EMC
Publication	
EN 1441	Medical devices - Risk Analysis

Quality System according to ISO 13485, as well as to Council Directive 93/42/EEC Annex II section 3, certified by Notified Body no. 1014 - Electrotechnical Testing Institute - Czech Republic, Pod Lisem 129, 171 02 Praha 8, certificate number MED 060016.

Validity for serial numbers: AA24XXX 2006

Praha 12. 1. 2006



Ing. Jiří Seidl
managing director