

EC Certificate Full Quality Assurance System 17/07002

The management system of

# Aerotel Medical Systems (1998) Ltd

19 Hamashbir Street  
Holon 5885325  
ISRAEL

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC on Medical Devices, Annex V

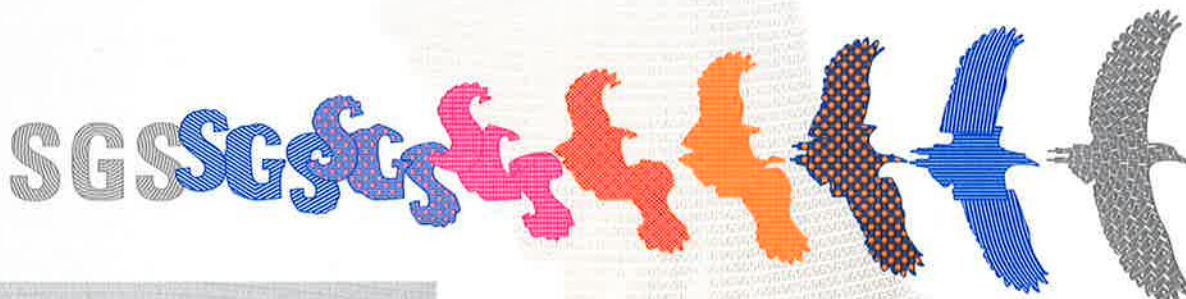
For the following products  
**ECG Recorders and ECG Data Management Software**

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 29 January 2019 until 14 March 2022  
and remains valid subject to satisfactory surveillance audits.  
Recertification audit due before 14 March 2020  
Issue 1. Certified since 14 March 2014  
This certification is based on decision: F117/07002P0

Authorised by

Seppo Vahasalo, Notified Body Manager  
SGS Fimko Ltd., Notified Body 0598



Aerotel Medical Systems (1998) Ltd  
19 Hamashbir Street  
Holon 5885325  
Israel

EC-certification application 2013-11-28

**Subject** Re-certification of quality system and product range, based on Council Directive 93/42/EEC concerning medical devices, Annex V Section 3

**Manufacturer** Aerotel Medical Systems (1998) Ltd  
19 Hamashbir Street  
Holon 5885325  
Israel

**Decision** A certificate will be issued for the manufacturer. The certificate covers the following products:

<b>Product</b>	<b>Model</b>	<b>Class</b>
ECG Recorder	HeartView P12/8i	Ila
ECG Recorder	HeartView 12L	Ila
ECG Recorder	HeartView 12i	Ila
ECG Recorder	HeartView P12/8 Mobile	Ila
ECG Data Management Software	HRS	Ila

**Justification** SGS Fimko Ltd has assessed manufacturer's quality management system and products. Quality management system and products meet the requirements of Annex V of Medical Device Directive 93/42/EEC. The decision is based on audit report(s) 273742.

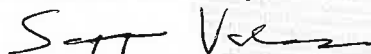
The manufacturer has signed the undertaking to follow the obligations of Annex V of the Directive 93/42/EEC.

**Certificate related to decision** FI17/07002, Issue 1

**Attachment to certificate** Attachment 1, Issue 1

**Valid until** This decision is valid until 14 March 2022 providing the requirements of the certification are fulfilled.

**Date** Helsinki, 29 January 2019



Seppo Vahasalo, Notified Body Manager  
SGS Fimko Ltd, Notified Body 0598

## Attachment 1, issue 1 to SGS Fimko Ltd. EC certificate FI17/07002, issue 1

<b>Manufacturer</b>	Aerotel Medical Systems (1998) Ltd
<b>Address</b>	19 Hamashbir Street Holon 5885325 ISRAEL
<b>Activity and Medical Device Product Category</b>	93/42/EEC Annex V ECG Recorders and ECG Data Management Software

List of medical devices and the corresponding type/model markings with product trademarks/marketing names covered by this certificate:

<b>Medical Device</b>	<b>Class</b>	<b>Trademark(s) and Model(s)/type(s)</b>
ECG Recorder	Ila	HeartView P12/8i
ECG Recorder	Ila	HeartView 12L
ECG Recorder	Ila	HeartView 12i
ECG Recorder	Ila	HeartView P12/8 Mobile
ECG Data Management Software	Ila	HRS

Authorised by



Seppo Vahasalo, Notified Body Manager  
SGS Fimko Ltd., Notified Body 0598

Date issued/revised: 29 January 2019