

S003 (EN ISO/IEC 17065)

EC Certificate Full Quality Assurance System FI20/871798

The management system of

VitalSignum Oy

Kuortaneenkatu 2 FI-00510 Helsinki Finland

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices, Annex II (excluding section 4)

For the following products

ECG recorders

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 23 July 2020 until 24 May 2024 and remains valid subject to satisfactory surveillance audits. Issue 1. Certified since 23 July 2020

This certification is based on decision: Fl20/07039P0

Authorised by

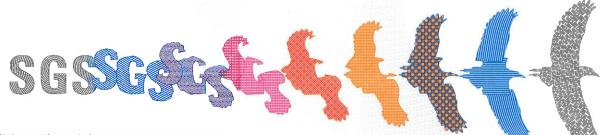
Seppo Vahasalo

Notified Body Manager

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Page 1 of 2





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Attachment 1 to SGS Fimko Ltd. EC certificate FI20/871798 Issue 1

Manufacturer	VitalSignum Oy		
Address	Kuortaneenkatu 2 Fl-00510 Helsinki Finland		
Activity and Medical Device Product Category	93/42/EEC Annex II (excluding Section 4) ECG recorders		

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

Medical Device	Class	Trademark(s) and Model(s)/type(s)	
ECG sensor	lla sessessesses	Beat2Phone ECG Sensor	
ECG application	lla sossosos	Beat2Phone ECG App version 2.X.X	