EC Certificate Full Quality Assurance System FI21/871845

The management system of

NE Device SW Oy

Teknologiantie 7B
90590 Oulu
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

Standalone software for measuring vital signs

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 20 May 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 20 May 2021
This certification is based on decision: FI21/07052P0

Authorised by

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

Seppo Vahasalo
Notified Body Manager

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Attachment 1 to SGS Fimko Ltd. EC certificate FI21/871845 Issue 1

Manufacturer	NE Device SW Oy
Address	Teknologiantie 7B 90590 Oulu Finland
Activity and Medical Device Product Category	93/42/EEC Annex II (excluding Section 4) Standalone software for measuring vital signs

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)
Standalone software for measuring vital signs	IIa	Vitacam V1