EC Certificate Full Quality Assurance System FI20/871801

The management system of

Nukute Oy

Mäkelininkatu 43
90100 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

Biosignal recorder for sleep disorder diagnostic aid

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 21 August 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 21 August 2020
This certification is based on decision: FI20/07047P0

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 FI20/871801 Issue 1

Manufacturer	Nukute Oy
Address	Mäkelininkatu 43 9010 Oulu Finland
Activity and Medical Device Product Category	93/42/EEC Annex II (excluding Section 4) Biosignal recorder for sleep disorder diagnostic aid

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)
Biosignal recorder for sleep disorder diagnostic aid	IIa	Nukute Collare