

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

Sapp Va

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	93/42/EEC Annex II (excluding Section 4)	
Device Product Category	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	lla	Nukute Collare
disorder diagnostic aid	SGSGSGSGSGSGSGS SGSGSGSGSGSGSGSGSGSGSGS	na na Galaga La Gala Nan San San San San San San San San San S

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