

S003 (EN ISO/IEC 17065)

EC Certificate Full Quality Assurance System Fl20/871801

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

Sagar Vac

Authorised by

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