VAATIMUSTENMUKAISUUSVAKUUTUS

Me,

Nukute Oy

Mäkelininkatu 43

90100 Oulu

Finland

vakuutamme, että

Nukute Collare

luokka IIa lääkintalaitedirektiivin 93/42/EEC säännön 10 mukaan

GMDN 36872: potilasmonitori, moniparametrinen, kannettava

täyttää

lääkintälaitedirektiivin 'Medical Device Directive 93/42/EEC', jota on viimeksi muutettu 2007/47/EC,

radiolaitedirektiivin (2014/53/EU),

tiettyjen vaarallisten aineiden käytön rajoittamisesta sähkö- ja elektroniikkalaitteissa direktiivin (2011/65/EU)

ja seuraavat harmonisoidut standardit

EN ISO 14971:2012: Terveydenhuollon laitteet ja tarvikkeet. Riskinhallinnan soveltaminen terveydenhuollon laitteisiin ja tarvikkeisiin

EN 62304:2006 / A1:2015: Medical device software – Software life cycle processes.

EN 60601-1:2006 / A1:2013: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

EN 60601-1-2:2015: General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests.

EN 62366-1:2015: Medical Devices. Application of usability engineering to medical devices.

EN 62366-2:2016: Guidance on the application of usability engineering to medical devices.

EN 60601-1-6:2010:1:2015: Medical electrical equipment- Part 1-6: General

requirements for basic safety and essential performance - Collateral standard: Usability

EN 10993-1:2011: Medical Devices – Biological evaluation of medical devices – Part 1: Evaluation and Testing

EN 60601-1-11:2015: Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical system used in the home healthcare environment

EN 301 489-1 v.2.1.1: ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU

EN 300 328 v.2.1.1: Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

ISO 14155:2011: Clinical Investigations of medical devices for human subjects – Good clinical practice

Ilmoitettu laitos on

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EC certificate number FI20/871801

25/08/2020, Oulu, Finland

Nukute Oy:n puolesta,

Allekirjoitus: 

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