DECLARATION OF CONFORMITY

We

Nukute Oy

Mäkelininkatu 43

90100 Oulu

Finland

declare under our sole responsibility that the

Nukute Collare

Medical device classification IIa according to rule 10 set out in Annex IX of Directive 93/42/EEC

GMDN 36872: patient monitor, multiparameter, transportable

is in conformity with the applicable

provisions of Council Directive 93/42/EEC as amended by 2007/47/EC concerning medical devices,

Radio Equipment Directive (2014/53/EU),

Restriction of the use of certain hazardous substances in electrical and electronic equipment Directive (2011/65/EU),

and the product is in conformity with the following standards:

EN ISO 14971:2012: Medical Devices. Application of risk management to medical devices.

EN 62304:2006 / A1:2015: Terveydenhuollon ohjelmistot – Ohjelmiston elinkaariprosessit

EN 60601-1:2006 / A1:2013: Terveydenhuollon laitteet – Osa 1: Yleiset vaatimukset turvallisuuteen ja suorituskykyyn liittyen

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

The Notified Body is

SGS Fimko Oy, 0598

Takomotie 8

00380 Helsinki

EC certificate number FI20/871801

25/08/2020, Oulu, Finland

On behalf of Nukute Oy,

Signature: _____

Toni Leinonen

CEO