

EC DECLARATION OF CONFORMITY



Product name: *Lumoral (02-001)*

Name and address of the manufacturer: *Koite Health Oy*
Otakaari 5 A 409
02150, Espoo

Classification (MDD, Annex IX): *Class IIa product, Rule 9 in Annex IX of the MDD*
93/42/EEC

Conformity assessment route: *Annex II (Full quality assurance system) of the MDD*
93/42/EEC

Directives:
93/42/EEC Medical Device Directive, amended by 2007/47/EC
629/2010 Laki terveydenhuollon laitteista ja tarvikkeista

Standards:

EN 60601-1:2006/A1:2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
EN 60601-1-6:2010/A1:2015	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
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 systems used in the home healthcare environment
EN 60601-2-57:2011	Medical electrical equipment - Part 2-57: Particular requirements for basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.
EN 60601-2-75:2017	Medical electrical equipment - Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment
EN 62366:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016)

EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General
EN 60529	Degrees of protection provided by enclosures (IP code)
EN 1041:2008	Information supplied by the manufacturer of medical devices

We declare under our sole responsibility that the above-mentioned product meets the provisions of the following Council Directives and Standards. All supporting documentation are retained under the premises of the manufacturer.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Koite Health Oy operates under Quality Management system, certified by SGS Fimko Ltd, notified body no. 0598, according to standard EN ISO 13485:2016, certificate no. FI21/871821 and Council Directive 94/42/EEC, certificate no. FI21/871843.

Place, Date:

Espoo, 2021-05-25

Signature:



Name:

Sakari Nikinmaa

Position:

CEO