

EU Declaration of Conformity

1. Name, SRN (if already issued) and address of the manufacturer or his authorized representative:

Koite Health Oy
FI-MF-000006901
Kutojantie 2C
02630 Espoo

2. This declaration of conformity is issued under the sole responsibility of Koite Health Oy.

3. Basic UDI-DI: 6429810197LumorinseCK

4. Object of the declaration:

Product: Lumorinse

Trade name: Dental Product

Risk Class: Class I according to Annex VIII, rule 5 of Regulation (EU) 2017/745

Intended Purpose:

Lumorinse is an effervescent tablet that is intended to be used together with Koite Health Lumoral light applicator device.

5. The object of the declaration described above is in conformity with the relevant Union legislation:

Medical Device Regulation 2017/745

6. References to the relevant harmonized standards used or references to the common specifications in relation to which conformity is declared:

EN ISO 14971:2012	Medical devices – Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN 62366-1:2015	Medical devices – Application of usability engineering to medical devices

7. Name and Identification of Notified Body:

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.

8. Signed for and on behalf of:

Date and place: 14.06.2023, Espoo

Manufacturer: Koite Health Oy



Sakari Nikinmaa, CEO

