

EU Quality Management System Certificate FI25/00000056

The management system of

Koite Health Oy

Koite Health Oy, Karaportti 5, FI-02610 Espoo, Finland SRN: FI-MF-000006901

has been assessed and certified as meeting the requirements of

Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

For the following products and activities

Devices for prevention and treatment of oral diseases caused or exacerbated by dental plaque

Issue 1

Previous certificate's number and issue: N/A

Change in between this certificate and the previous one: N/A

The devices covered, their risk classifications, codes applied, identification details, intended purposes, standards and common specifications followed, conditions or limitations, as well as applicable test and audit reports referred to, are listed on the subsequent pages of this certificate.

This certificate is valid from 24 October 2025 until 06 October 2028 and remains valid subject to satisfactory surveillance audits.

Certified since 24 October 2025

Certified activities performed by additional sites are listed on the subsequent pages.



Authorised by

Seppo Vahasalo, NB Manager

SGS FIMKO OY

Notified Body 0598 Takomotie 8, FI-00380 Helsinki, Finland

t +358 9 696 361 - www.sgs.fi - Business ID 0634247-4



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Koite Health Oy

Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

Issue 1
Sites
Karaportti 5, FI-02610 Espoo, Finland
Devices for prevention and treatment of oral diseases caused or exacerbated by dental plaque

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Attachment 1 of Issue 1
Risk classes, codes, identification, and other relevant details of the certified devices:
Risk class IIa MDA 0311, MDS 1009 EMDN Z12040202 PHOTOTHERAPY EQUIPMENT Lumoral Treatment, Basic UDI-DI 6429810197LumoralTreatmP6 Lumoral Junior, Basic UDI-DI 6429810197LumoralJunioB8 Lumoral Clinic, Basic UDI-DI 6429810197LumoralClini66 Accessory: Lumorinse, Basic UDI-DI 6429810197Lumorinsetabl4P Accessory: Power bank, Basic UDI-DI 6429810197LumoralPowerbQ7
The certification decision is based on the following:
Report Identification and Date: Audit report: Audit report: FIMED297531 Koite Health Oy V1_S2 2024 - FPMREG3019 - MD Audit Report Ver F - rev 3 dated 2025-10-06 Technical documentation assessment report: FIMED297531 Koite Health Oy 2024 TDA FPMREG3020 - MDR Technical Documentation Assessment Report Rev 3 dated 2025-10-06 Notification of Change Report: FIMED297531 Koite Health Oy FPMREG1008 - MDR Notification of Product Changes Ver F 2025-10-20_reviewed_2025-10-23 Applied Standards / Common specifications: EN ISO 13485:2016 + A11/2021, EN ISO 14971:2019 + A11/2021, references to other relevant CS and harmonized standards are in the reports Conditions for or limitation to the validity of the certificate: PMCF to be completed for the use of the device with children. EU Authorised Representative: N/A