EC declaration of conformity

ANNEX VII DIRECTIVE 93/42/CEE of June 14th 1993

Concerned product:

PURESSENTIEL HEADACHE MIGRA PURE® ROLL-ON
CLASSE I

GMDN code: 34661, Manual massager, home-use

Laboratoire PURESSENTIEL IRELAND Ltd ensures and declares that:

1. The product PURESSENTIEL HEADACHE MIGRA PURE® ROLL-ON, meets 93/42/EEC directive applicable Essential Requirements.
2. The technical documentation described in Section 3; Annex VII of 93/42/EEC directive was prepared. This documentation, including the declaration of conformity, will be available to the national authorities for inspection purposes for a period ending at least five years after the last product has been manufactured.
3. A systematic procedure will be instituted and kept up to date to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product.
4. The competent authorities will be notified of the following incidents immediately on learning of them:
    a. Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health.

    b. Any technical or medical reason connected with the characteristics on the performance of a device for the reasons referred to in subparagraph (a) leading to systematic recall of devices of the same type by the manufacturer.

This declaration allows Puressentiel to affix the CE marking on PURESSENTIEL HEADACHE MIGRA PURE® ROLL-ON medical device starting from the 01st of April 2018.

25th of October 2023

Coralie YOROA, Regulatory Affairs Coordinator

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