Disclaimer

REGULATORY COMPLIANCE, INTENDED USE AND SAFETY GUIDELINES

deepLive™ is a Class IIa medical device according to European Regulation 2017/745. The CE certificate was issued by GMED (notified body n°0429) in 2023.

deepLive™ is manufactured in France and distributed by Damae Medical.

deepLive™ is intended to be used as a non-invasive imaging tool in the evaluation of external human tissue microstructure by providing three-dimensional, cross-sectional and en-face real-time depth visualization for assessment by physicians to support in forming a clinical judgment.

deepLive™ is notably indicated to support dermatologists in the diagnosis of equivocal basal-cell carcinoma (BCC) lesions, and in the assessment of other skin cancers, including squamous-cell carcinomas (SCC) and melanoma skin cancers (MM). Published clinical data has reported an aggregate accuracy of 97% of dermatologists using **deepLive™** for the diagnosis of BCC.

The device includes an optional hand-held dermoscope accessory which provides wide-field color video images of the surface of the skin.

The device also includes an optional deep learning algorithm designed to distinguish basal cell carcinomas from their most common clinical imitators, offering real-time assistance during skin lesions examination with **deepLive™**. The AI assistant is trained to predict whether or not there is a suspicion of BCC presence at the frame-level on LC-OCT vertical images, and returns a score of probability along with an optional color-coded attention map showing the areas in the images used by the algorithm to perform the prediction. The AI is an adjunctive second-read device following identification of a suspicious basal cell-carcinoma lesion.

deepLive™ is contraindicated for invasive procedures, as the part in contact with the patient must be applied only on intact skin area, and not on mucosal membranes or breached skin, because of biological risks. The device is also contraindicated for ophthalmic procedures, as the system must not be used on the patient's eye, because of laser radiation risks. A safety distance from the eye border is recommended.

deepLive™ must be used only by intended user profiles, namely medical practitioners who were trained to operate the device, on the targeted population, namely all-ages patients presenting suspicious skin lesions, in the context of a clinical study or medical examination, and not as a screening tool.

Images obtained with **deepLive™** must be assessed by physicians experienced in dealing with the diagnosis and management of dermatologic pathologies, in conjunction with the totality of relevant clinical information about the patient. It is not for use as a standalone diagnostic.

It is expressly recommended to carefully read the guidance and instructions for use available in the user manual and labeling of the device. Any serious incident occurring with the device shall be notified to the manufacturer or its local representative, and the appropriate competent authority.

In the event of breakdown or damage to the device, only a maintenance team authorised the manufacturer may work on the device. Under no circumstances should the user attempt to open the product, as this could be dangerous.

Safety and performance of **deepLive™** have been evaluated and validated in accordance with product specifications and applicable standards through verification, validation, performance and safety testing.

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