**PRESS RELEASE**

***For immediate release***

# Damae Medical's deepLive™ imaging device for non-invasive skin cancer diagnosis receives CE Mark Class IIA under EU MDR 2017/745

- **The deepLive™ non-invasive device, invented by Damae Medical, is among the first group of medical devices to meet the new, high-standard qualifications required to achieve the latest EU MDR CE mark Class IIA.**
- **The deepLive™ is a medical imaging device intended to provide 3D in vivo images during in-depth study of the skin and cutaneous cancers to assist dermatologists with clinical pathology diagnostics.**
- **One of the indications of deepLive™ is the management of equivocal basal cell carcinoma lesions with clinical benefits for patients including avoidance of unnecessary and invasive biopsy or surgery.**

**Paris, France, March 2, 2023 - Damae Medical**, a developer of innovative imaging devices and artificial intelligence solutions for diagnostic support of dermatologists, receives the CE mark Class IIA in accordance with new EU Medical Device Regulation 2017/745 for deepLive™, their best-in-class imaging system. The CE marking was granted by the French notified body GMED.

Following recent elevation of the standards required to receive the distinguishment, the previously CE marked Class I deepLive™ device underwent additional testing and extensive evaluation in order to satisfy the comprehensive requirements of the EU MDR. The progression from Class I to Class IIA is a key milestone as deepLive™ combines previous uses in clinical research with advancements in diagnostic support. Few other medical devices have accomplished this feat following the implementation of MDR's new standards for superior quality management, putting Damae Medical in an exclusive group of companies representing the future of medical device technology in Europe.

deepLive™ revolutionizes the management of skin cancer by using 2D and 3D real-time imaging and measurement of skin and tissue microstructures to aid dermatologists in the management of their patients of all ages and skin types. Damae Medical's imaging device is indicated for screening and diagnosis of equivocal basal cell carcinoma lesions with a sensitivity of 98% and a specificity of 81% as compared to traditional histology-stained images obtained from either biopsy or surgery. deepLive™ is also capable of visualization of the discriminating features of other skin cancers, including squamous cell carcinoma and melanoma, as well as inflammatory diseases.

**David Siret, Co-founder and Chief Technical Officer of Damae Medical, says of the accomplishment:** *"The new CE-marking is a key milestone in Damae Medical's road to success. Thanks to extended medical claims, it will boost the adoption of our innovative technology into the clinical routine of dermatologists. This initial MDR CE certification of deepLive™ provides a strong basis for faster regulatory clearance of new innovative features, and will significantly facilitate the compliance to other international regulations, such as FDA."*

**Anaïs Barut, co-founder and CEO of Damae Medical, added:** *"This immense accomplishment attests not only to Damae Medicals' commitment to continued excellence, but also to the dedication and agile operation of our entire team and partners. This initial CE MDR certification is key for deepLive™ to continue to directly support clinicians by boosting medical performances, especially in terms of increased sensitivity and specificity compared to traditional clinical examinations. The ability of deepLive™ to be seamlessly incorporated into both public and private clinical workspaces will maximize aid to providers as well as ease patient burdens. Looking at the long term, the Class IIA mark demonstrates our ability to meet quality standards while continuing to achieve efficient, high-level innovations in skin cancer management."*

CE-marked Class I and commercially available since 2020, deepLive™ has demonstrated its success in the realm of clinical research, having been deployed in key strategic university hospitals and leading clinical centers, resulting in a current installed base of over 40 units worldwide. With the issuance of the Class IIA labelling for diagnostic support, Damae Medical is looking towards the future to fast-track the widespread deployment of its innovative solutions to private practice dermatologists.

**About Damae Medical**

Damae Medical is reinventing skin imaging, revolutionizing the screening, management, and follow-up of skin cancers (melanoma and carcinoma) with its deepLive™ solution, which provides an accurate, fast and reliable optical examination without performing a biopsy.

CE marked, the deepLive™ medical device is based on LC-OCT (Line-field Confocal Optical Coherence Tomography) proprietary optical imaging technology that provides 3D images of the different layers of the skin at the cellular level, complemented by several software and Artificial Intelligence (AI) modules.

This innovation is protected by 6 patent families and has already been published in more than 80 scientific and medical publications.

Present in 10 countries and used in more than 40 referral centers, deepLive™ transforms the daily practice of dermatologists making the management of skin pathologies efficient, reassuring, and non-invasive for the patient. The product is also used by leading cosmetic and pharmaceutical players for research and evaluation purposes.

Based in Paris, Damae Medical currently employs 30 people. Winner of several innovation awards (MIT Technology Review, Bpifrance, European Commission), the company has been able to invest more than €20 million since its creation in 2014.

**www.damae-medical.com**

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