



Body Clock Health Care Limited

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### Manufacturer's Product Liability Notice – May 2025

PANAHCE HEALTHNEEDS PVT Ltd. is the exclusive licensed distributor in India of a range of medical devices marketed as "ELLE TENS" by our company Body Clock Health Care Limited and holds the official Ministry of Health MD15 certification.

As the legal manufacturer of the ELLE TENS product range, Body Clock Health Care Ltd. has exclusively granted PANAHCE HEALTHNEEDS PVT Ltd. the rights to use our international trademarks within India, in recognition of their adherence to the highest standards in the Indian market. Your current marketing of the 'ELLE TENS' product constitutes unauthorized use of our trademarks.

As the legal manufacturer for our TENS and EMS medical devices and all of their accessories e.g. electrodes, we have undertaken rigorous testing (e.g., biocompatibility, electrical safety, usability), which have been reviewed/audited by our Notified Body SGS before issuing Certification.

Certification and/or a copy of a Body Clock issued signed Declaration of Conformity, are legal documents required to legitimately register and place these medical devices on to the market, although additional local regulatory requirements may also apply.

If any of our medical devices are used in combination with other medical devices such as electrodes, sourced from alternative suppliers or if the information supplied with our medical devices (our user manual / Instructions for Use (IFU)) are amended, then these are not covered by our Certification nor our Declarations of Conformity.

Accessories obtained from other suppliers have not been assessed and not only would their use make our **warranty null and void**, but they would **not be covered under our Public Liability Insurance**. You would need to obtain your own insurance for those other medical devices.

If you choose to supply alternative accessories including medical devices, or alternative information with our medical devices (the user manual / IFU) or own brand any medical devices or accessories, this can only be achieved by you taking on full legal manufacturer responsibility yourself. This means commissioning your own testing, creation of full technical documentation, obtaining appropriate regulatory approvals and registrations (including with your own Notified Body) **BEFORE** placing your device on the market. **Failure to do so, renders the product you are seeking to market, illegal.**

Additionally, the use of non-original parts constitutes a breach of Ministry of Health regulations and exposes you personally to legal proceedings. Marketing and distributing the product without official authorization may result in the denial of insurance coverage for any kind of damage and even revocation of Ministry of Health recognition.

Moreover, unapproved, and inaccurate user instructions, which deviate from the Manufacturer's guidelines, harms the product's performance and the trust in it among the target consumers. Body Clock Health Care Ltd. do not give permission for any entity to copy our IFUs or to use excerpts to create their own IFUs. In doing so renders them a copyright infringement.

