

Evaluation report on compliance with HTA licensing standards

Report date: **27 January 2025**



Biofortuna Limited
HTA licensing number 12688

Licensed under the Human Tissue Act 2004

Licensed activities

Biofortuna Limited

- Storage of relevant material which has come from a human body for use for a scheduled purpose

Evaluation summary

At the HTA's request, the establishment submitted a self-assessment for evaluation of compliance against the HTA's licensing standards.

Evaluated self-assessments are intended to be proportionate and risk-based. They are one of several tools that the HTA uses to maintain regulatory oversight. The regulatory framework places responsibility for compliance with those undertaking regulated activities. Designated Individuals are responsible for the accuracy of self-assessments.

As part of this process, the Designated Individual (DI) reported the establishment (HTA licensing number 12688) was compliant with applicable HTA licensing standards. Based on the assurances provided, the HTA takes overall compliance to be satisfactory.

The HTA cannot provide any guarantees or endorsements of licensed establishments, or their activities, based on self-assessments.

The frequency and format of future assessments of compliance will be determined by the HTA according to evaluated risk.

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