

CERIBELL, INC.

Ceribell Quality & Safety Commitment

Quality Management System: Ceribell operates a rigorous Quality Management System certified to **ISO 13485** standards. This enables every device we manufacture to meet global regulatory requirements.

- **Regulatory Compliance:** We maintain full compliance with FDA (US) and CE Mark (EU) health authority regulations.
- **Post-Market Surveillance:** We utilize post-market surveys and other methods to assess performance of the Ceribell System in real-world settings.
- **Transparency:** We are committed to transparency regarding product safety. We maintain a formal process for adverse event reporting and recall management, prioritizing patient safety above all else.
- **Clinical Integrity:** All clinical trials sponsored by Ceribell are conducted in accordance with the **Declaration of Helsinki** and Good Clinical Practice (GCP) guidelines.