Statement of Clarification: Exomind in *Vogue* and Other Media Sources

Exomind (BTL Industries LTD.) is a transcranial magnetic stimulation (TMS) device that has recently been highlighted in media outlets, including *Vogue*, and advertised by medical spas as a wellness intervention. **TMS has strong evidence as a medical treatment for specific neurological and psychiatric diagnoses, but it does not have strong evidence as a performance enhancer or wellness intervention.**

- <u>FDA-cleared indications for TMS are limited to specific brain illnesses.</u>
  In the United States, TMS devices are FDA-cleared for major depressive disorder, depression with anxious features, obsessive-compulsive disorder, migraine, and smoking cessation. TMS does *not* have FDA-cleared indications for perimenopausal symptoms, "brain fog," binge eating disorder, "focus," or other conditions mentioned in the article.
- <u>Exomind does not have any unique use beyond other TMS devices.</u>
  Exomind received FDA clearance through the 510(k) substantial equivalence pathway. This clearance indicates that Exomind was deemed to be "substantially equivalent" to previously marketed TMS devices. However, a 510(k) clearance by itself *does not establish clinical efficacy for new indications* and does not require clinical trial data establishing clinical efficacy.
- <u>There are no peer-reviewed clinical trial data supporting the broad claims in the article.</u>
  The "clinically shown" link in the article refers to a public trial registry that describes a study design but does not report study results. As of January 2026, no peer-reviewed publications have demonstrated that the Exomind device or its protocol are effective for the wide range of conditions mentioned.

Promotional claims for Exomind or other TMS devices that extend beyond the available scientific evidence risk misleading the public and undermining trust in robust evidence supporting TMS as a medical treatment.