



To Whom It May Concern:

VersaWrap[®] contains no human tissue or human cells and is not a human cell-based or a human tissue-based product. Therefore, the product is not subject to the Food and Drug Administration (FDA) regulations for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) per 21 CFR 1271, including the tissue tracking and traceability requirements.

VersaWrap[®] is a non-tissue, non-animal class II medical device implant cleared via 510(k) pathway and regulated per 21 CFR 820.

Sarah Mayes, PhD

A handwritten signature in blue ink that reads "Sarah Mayes". The signature is fluid and cursive, with the first name "Sarah" and the last name "Mayes" clearly distinguishable.

Chief Scientific Officer