European Medical Device Regulation (EU MDR) Statement

February 9, 2024

To Our Valued Customers:

The following statement references EU MDR – REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND COUNCIL OF 5 APRIL 2017 Section 10.4 EU Classification, Labelling and Packaging (EC) No 1272/2008 for substances which are carcinogenic, mutagenic or toxic to reproduction (CMR), of category 1A or 1B, Annex VI to CLP ATP 19, mandatory on *31-July-2023*.

EU REACH (EC) No 1907/2006 for substances having endocrine-disrupting (ED) properties for human health, published in accordance with Article 59 (10) of the REACH Regulation, updated *12-January-2023*.

The Biocidal Products Regulation (BPR), Regulation (EU) 528/2012 for substances having endocrine-disrupting (ED) properties for human health, updated *15-April-2022*.

K-Tube Technologies is a manufacturer and distributor of laser-welded tubing and does not melt or produce any of the raw materials used in our products.

K-Tube Technologies acknowledges that the raw materials used for our products may contain the metal, Cobalt. Cobalt is not an intentional ingredient in stainless steel, and Cobalt-free stainless steel is not commercially available.

Cobalt is listed as a 1B substance for both carcinogen and reproductive toxicity. While Cobalt is not an intended ingredient for stainless steel, our records indicate that we have received stainless steel materials with cobalt levels between 0.00% to 0.42%.

No other substances are classified as 1A or 1B or endocrine disruptors (human health).

K-Tube does not intentionally add or use substances listed as 1A/1B CMRs or Eds as part of the manufacturing or handling of materials at levels above the 0.1% w/w threshold.

This declaration applies to all parts manufactured by K-Tube Technologies.

Regards,

Michael Carey

Michael Carey, EHS Engineer