EU MDR Statement on CMR and Endocrine Disrupting Substances Statement

Issued: December 20, 2021

Wire Products: Nitinol #1, Nitinol #2, Nitinol #3, Nitinol #4, Nitinol #5, Nitinol #6, Nitinol #8, Nitinol #9. This statement excludes research and development and prototype projects and material.

Fort Wayne Metals Research Products, LLC (FWM) has reviewed the European Union Medical Device Regulation (EC) No 2017/745 of April 5, 2017 “EU MDR” provisions concerning the carcinogenic, mutagenic, and reproductive toxic substances (CMR) restrictions/requirements. For more information on EU MDR, please visit https://ec.europa.eu/growth/sectors/medical-devices_en

In most instances, FWM provides to you raw material and/or components and, as a result, the EU MDR regulation applying to medical devices, are not applicable to FWM’s products. However, we understand the challenges you are facing and the need to identify the materials contained in your products. Product users are responsible for determining the applicability of EU MDR based on their individual usage of its final product.

CMR & Endocrine Disrupting Substances:

After review of Section 10.4 of the EU MDR addressing CMR and endocrine disrupting substances, to the best of FWM’s knowledge the Products listed above do not contain carcinogens, mutagens, or reproductive toxins category 1A or 1B as listed in Annex VI to CLP ATP15, except for cobalt in Nitinol #3, or substance of very high concern (SVHC) above 0.1% w/w. Nitinol #3 cobalt content exceeds 0.1% w/w. Please note, FWM used the weight of the article to evaluate the substances.

Please refer to the FWM website at https://www.fwmetals.com/about/corporate-responsibility/product-stewardship/customer-documents/ or submit a request for information to your FWM customer service associate, if new CMRs or SVHCs are published by the European Chemical Agency (ECHA) for updated information.

The information contained herein is for reference only and, to FWM’s knowledge, accurate as of the date of publication. As a custom manufacturer, we require our customers specify their preferred products. As such, it is the customer’s responsibility to inspect and test our products in order satisfy itself as to the suitability of the products for the customer’s particular purpose and suitability to the actual circumstances the product is exposed to. Likewise, you (the customer) are also responsible for the appropriate, safe, and legal use, processing and handling of our products in your facilities and your final product(s). This statement shall not be considered a warranty of any kind as FWM’s sole warranty for its product(s) is set forth on the Purchase Order Acknowledgement’s Terms & Conditions of Sale or as otherwise agreed to, in writing.
CMR category 1A and 1B and SVHC substance determination is based on internal product review process. Any provided material content data, if applicable, is not to be considered a warranty or quality specification.

This statement substitutes all previous version issued for the above listed Products.

Fort Wayne Metals Research Products, LLC
Product Stewardship Team

The information contained herein is for reference only and, to FWM’s knowledge, accurate as of the date of publication. As a custom manufacturer, we require our customers specify their preferred products. As such, it is the customer’s responsibility to inspect and test our products in order satisfy itself as to the suitability of the products for the customer’s particular purpose and suitability to the actual circumstances the product is exposed to. Likewise, you (the customer) are also responsible for the appropriate, safe, and legal use, processing and handling of our products in your facilities and your final product(s). This statement shall not be considered a warranty of any kind as FWM’s sole warranty for its product(s) is set forth on the Purchase Order Acknowledgement’s Terms & Conditions of Sale or as otherwise agreed to, in writing.
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