

Fort Wayne Metals Research Products, LLC

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**FORT WAYNE METALS**

F-LE-81 Rev February 5, 2025

Nitinol Product Statement

Products include: Nitinol #1, Nitinol #2, Nitinol #3, Nitinol #4, Nitinol#5, Nitinol #6, Nitinol #8, and Nitinol #9

This statement excludes research and development and prototype projects and materials.

Fort Wayne Metals Research Products, LLC (FWM) product, when shipped, meets or exceeds the following statements:

EU RoHS, RoHS 2, RoHS 3 Compliance (EU Directive 2015/863):

The products listed above do not contain intentionally added Substances above the RoHS, RoHS 2, RoHS 3 stated concentration limits.

EU REACH Compliance (Regulation EC/1907/2006):

The products listed above do not contain intentionally added REACH Substances of Very High Concern (SVHC) as listed in the January 21, 2025 (247 SVHC) list, in concentrations above 0.1% weight by weight.

REACH Restriction List (Annex XVII): The above listed products contain Nickel in concentrations of 54.5 – 57.0% w/w.

Latex:

FWM does not use or intentionally add natural rubber latex for the production of the above products.

Bisphenol A (BPA):

FWM does not use or intentionally add BPA for the production of the above products.

Phthalates:

FWM does not use or intentionally add phthalates for the production of the above products.

Nanomaterial:

FWM does not use or intentionally add nanomaterials as defined in Regulation (EU) 2017/745 for the production of the above products.

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.

EU MDR CMR & Endocrine Disrupting Substances:

The products listed above do not contain endocrine disrupting substances or carcinogens, mutagens, or reproductive (CMR) toxins category 1A or 1B as listed in Annex VI to CLP ATP21 (Regulation (EU) 2022/692) in concentrations above 0.1% weight by weight (w/w), except for cobalt in Nitinol #3. Nitinol #3 cobalt content is 1% to 2% w/w.

Polyvinyl Chloride (PVC):

FWM does not use or intentionally add polyvinyl chloride (PVC) for the production of the above products.

EU Biocidal Products Regulation:

FWM does not use or intentionally add biocidal products identified in Regulation (EU) 528/2012 for the production of the above products.

Antimicrobial Agents:

While we have “cleaning processes”, they are not intended to be a final clean to any standard but rather an in-process step to remove excess processing agents. The biocompatibility of our products is not certified from our facility and must be evaluated through clinical studies conducted by the final device manufacturer.

Human Derived Material:

FWM does not use or intentionally add Human Derived Material as defined in EU Directive 2004/23/EC for the production of the above products.

EU Persistent Organic Pollutants (POPs):

FWM does not use or intentionally add persistent organic pollutants (POPs) as defined in Regulation (EU) 2019/1021 and Regulation (EU) 2022/2400 for the production of the above products.

The information in this statement is based on information provided by our suppliers and from random sample testing by outside accredited laboratories.

Fort Wayne Metals Research Products, LLC
Product Regulatory Team

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