Fort Wayne Metals Research Products, LLC
9609 Ardmore Avenue
Fort Wayne, IN 46809
U.S.A.

PHN +00 (1) 260 747 4154
FAX +00 (1) 260 747 0398

Fort Wayne Metals Ireland Ltd.
IDA Business & Technology Park
Breaffy Road, Castlebar, Co. Mayo, F23 TF61
Ireland

PHN +353 (0) 94 90 43500
FAX +353 (0) 94 90 43555

FORT WAYNE METALS

F-LE-81 Rev November 18, 2026

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 February 4, 2026 (253 SVHC) list, in concentrations above 0.1% weight by weight.

REACH Annex XIV: The products listed above do not contain substances listed on the REACH Authorization list.

REACH Restriction List (Annex XVII): The above listed products contain Nickel (CAS # 7440-02-0) 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.

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.

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

EU MDR CMR & Endocrine Disrupting Substances (Regulation (EU) 2024/2564 & 2022/692):
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 ATP 23 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 (Regulation (EU) 528/2012)
FWM does not use or intentionally add biocidal products 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 (EU Directive 2004/23/EC):
FWM does not use or intentionally add Human Derived Material for the production of the above products.

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

Packaging and Packaging Waste Regulation (PPWR 2025/40/EU)):
All FWM packaging and its materials are in conformity with the PPWR:

And the sum of the concentrations of

- Lead (Pb)
- Mercury (Hg)
- Cadmium (Cd), and
- Hexavalent Chromium (Cr6+)

Resulting from substances present in packaging or packaging components does not exceed 100 mg/kg.

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.

California Prop 65:
Above listed products contain Nickel (CAS # 7440-02-0) in concentrations of 54.5 – 57.0% w/w.

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

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.