



Sussex Wire

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Sussex Wire d/b/a MW Components – Easton
Palmer Industrial Park
4 Danforth Drive
Easton, PA 18045-7820

January 5, 2024

Regulation (EU) 2017/745 Declaration of Compliance Information Request Response

To our valued customers,

The intent of this letter is to inform Sussex Wire d/b/a MW Components – Easton’s valued customers how Sussex Wire d/b/a MW Components - Easton will respond to all requests for information pertaining to Regulation (EU) 2017/745.

Sussex Wire d/b/a MW Components – Easton thoroughly understands these requirements and is committed to environmental and personal health, however, due to the extensive number of part numbers and materials used, we cannot provide blanket statements of conformance and/or detailed responses for each item upon request. Sussex Wire d/b/a MW Components -Easton is committed to comply with all United States laws and regulations as well as all other countries laws and regulations where our parts are supplied. These laws and regulations change based on the country in which the parts are to be supplied. We are committed to follow all requirements per each country’s laws and/or regulations. Due to this, Sussex Wire d/b/a MW Components -Easton will not respond to blanket or specific requests for information without a valid purchase order for said part number. Additionally, as a contract manufacturer we do not control the designs of any parts manufactured at our facility. Due to this, it is our customer’s responsibility to specify the required material for each part. Within the limitations of all United States laws and regulations and when it is safe for our employees to be exposed to said materials/substances, Sussex Wire d/b/a MW Components – Easton will follow said specifications or notify our customers prior to manufacture, that we cannot utilize said material/substance.

It is our policy that all regulatory and statutory requirements be documented on the customer’s purchase order and/or associated engineering documentation/specifications. Sussex Wire d/b/a MW Components – Easton will review all associated documentation at time of order acceptance to ensure compliance to all applicable regulatory, statutory, and customer specific requirements. At the time of shipment, a Certificate of Conformance will be generated stating compliance to the applicable requirements with the verbiage:

“The above part(s) have been produced and supplied in accordance with all contractual/purchase order requirements. Further, said part(s) have been produced and supplied in accordance with all applicable drawings, specifications, and/or engineering documentation.”

Specifically pertaining to Regulation (EU) 2017/745, Sussex Wire d/b/a MW Components - Easton will provide a detailed chemical analysis of all raw materials contained within the part(s) shipped and certify conformance to the appropriate regulations. The declaration on the next page of this document will be posted at <https://www.mwcomponents.com/compliance/easton>. It is only applicable when the customer PO or associated engineering documentation states compliance to Regulation (EU) 2017/745. Should you have any questions regarding this letter, or the declaration included, please contact me directly at tarnold@mwcomponents.com.

Respectfully,

Tyler Arnold

Quality Manager/Compliance Officer

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Regulation (EU) 2017/745 Declaration of Compliance

To whom it may concern,

This declaration is to inform customers of Sussex Wire d/b/a MW Components – Easton, that products produced by Sussex Wire d/b/a MW Components – Easton conform to the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Sussex Wire d/b/a MW Components – Easton certifies that it gathered the required information, and such information is true and correct to the best of our knowledge and belief. Sussex Wire d/b/a MW Components - Easton relies on the certification of their suppliers in determining the compliance of our products. Sussex Wire d/b/a MW Components - Easton has relied on information provided by others in completing this declaration, and that the information has not been independently verified. However, Sussex Wire d/b/a MW Components - Easton's suppliers have provided certifications regarding their contributions to the part(s), and those certifications are at least as comprehensive as this declaration. If Sussex wire d/b/a MW Components - Easton enters into a written agreement, the terms and conditions of that agreement, including any warranty rights and/or remedies provided as part of that agreement, will be the sole and exclusive source of Sussex Wire d/b/a MW Components – Easton's liability, and the Company's remedies for issues that arise regarding information supplied in this declaration.

The list of chemicals which the European Parliament's risk assessment process has determined to present a risk can be found at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745>.

Sussex Wire d/b/a MW Components – Easton is committed to complying with all applicable laws and regulations. Sussex Wire d/b/a MW Components – Easton will continue to monitor all applicable laws and regulations and assess any changes for their impact to this declaration.

1/5/2024

X

Tyler Arnold
Quality Manager/Compliance Officer
Signed by: Tyler Arnold