

CONFORMITY STATEMENT MEDICAL DEVICES

This conformity statement applies to the following products as supplied to Global Express Trading:

<u>Item</u>	<u>Description</u>
• F83010509	PDC F830 Muraculon Clear
• F87410509	5-Gallon F874 Clear
• F97020509	PDC® F-970 eccs®

Plasti Dip International manufactures a wide variety of specialty coatings that our customers find useful for a broad range of applications, including the manufacture of component parts of regulated Class I medical devices intended for limited, prolonged, or permanent contact with the intact surface of the skin. While we do not purposefully manufacture or test our products for such applications, it is our expectation that the products listed above, when fully cured, will not be considered cytotoxic, irritating, or sensitizing when tested according to the protocol specified in ISO 10993 "Biological Evaluation of Medical Devices" or when similarly tested to meet applicable UK Medicines and Healthcare Products Regulatory Agency (MHPR) regulations. In addition, the above-listed products are not known or expected to contain any substances that may be banned or that may otherwise render the product unsuitable for such applications, such as lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers, polychlorinated biphenyls, arsenic, natural latex, or other known allergens that may be bioavailable.

This conformity statement is intended to be used as part of the medical device manufacturer's own conformity assessment, including for purposes of "UKCA" marking in the UK, and should not be viewed as a replacement for actual testing that may be required or that may otherwise be considered necessary to ensure patient safety. In addition, this statement only applies to the products listed above, as supplied by Plasti Dip International and after they are fully cured, when used as a component of an otherwise conforming class I medical device intended for limited, prolonged, or permanent contact with the intact surface of the skin.

Plasti Dip International is fully committed to assisting all of our customers in their ongoing efforts to comply with applicable regulations. As such, should you become aware of any health or safety concerns relating to the use of our products in medical devices, we ask that you notify us immediately.

Stated this 2nd day of June, 2022 by:

Plasti Dip International
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Blaine, MN 55449
763-795-6115