REGULATORY LETTER

The Thermoplastics You Need. The Service You Deserve.

RE: EU MDR - Medical Device Regulation (EU Reg: 2017/745) Letter - Polifil® Products (January 26, 2025)

To Whom It May Concern:

This correspondence is in response to your request for a statement regarding the content of hazardous substances listed in EU MDR - Medical Device Regulation (EU Reg: 2017/745) in Polifil® products manufactured by The Plastics Group.

The Plastics Group certifies that all Polifil® products and components used in their formulation do not contain, nor are they knowingly produced with any substances listed in the EU MDR - Medical Device Regulation (EU Reg: 2017/745) January 26, 2025.

The MDU - Hazardous Substances listing can be found at:
https://echa.europa.eu/eu-medical_devices-anx_i_7_8

If you have any questions or need anything further please feel free to contact us directly at (401) 767-2700 or e-mail us at compliance@plasticsgroup.com.

Thank you for your continued interest in Polifil® products and services.

The Plastics Group of America

The Plastics Group of America
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