

ProVital+

Medical Grade Masterbatch Solutions

consistency, conformity and expertise

- Designed with raw materials pre-tested for **biocompatibility** under ISO 10993:2021
 - Cytotoxicity part 5
 - Sensitization part 10
 - Irritation part 23
- **European Pharmacopoeia** and **USP 661.1** testing depending on application and market requirements
- Consistency of formulation
- No change policy for raw materials at CAS and trade name level

- Control of incoming raw materials
- Consistent process parameter window
- Production in controlled room environment
- Manufactured at **ISO 13485** certified sites
- Notification of Change
- FDA Drug Master File access
- Support documentation on ICHQ3D
- Extended polymer expertise
- Applications: medical devices, in-vitro diagnostic equipment, primary pharmaceutical packaging

ProVital+ White Masterbatch Solutions

Ampacet ProVital+ Whites are high-performance, medical-grade masterbatches specifically engineered for the opacification and coloration of primary and secondary pharmaceutical packaging, medical devices, and in-vitro diagnostic (IVD) equipment.

Formulated to meet the rigorous standards of the healthcare sector, **ProVital+ Whites** comply with stringent regulatory requirements to ensure safety, consistency, and reliability.

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ProVital+ Color Masterbatch Solutions

The **Ampacet ProVital+ Color** range offers both standard and custom-designed medical grade masterbatch solutions, available in translucent and opaque formulations. These masterbatches are engineered to support a wide range of conversion processes.

To shorten time to market, customers are welcome to collaborate at Ampacet Ideation Center, a one-stop facility staffed by color, technical, and regulatory experts dedicated to accelerating product development and reducing time to market.

AMPACET

ProVital+ Additive Masterbatch Solutions

ProVital+ Permstat

Ampacet ProVital+ PERMSTAT is a medical grade non-migratory antistatic masterbatch solution specifically developed to provide immediate and permanent antistatic properties to polyolefin films used for pharmaceutical packaging (i.e. cleanroom and API transfer bags).

ProVital+ Gamma-Protect

Ampacet ProVital+ Gamma-Protect is a medical-grade additive system designed to stabilize polyolefins during gamma or e-beam sterilization, preventing post-sterilization degradation and preserving the polymer's mechanical and optical properties.

ProVital+ Gastop-Flex

Ampacet **ProVital+ GASTOP-FLEX** is a high-performance, medical-grade masterbatch formulated to improve the barrier properties of polyolefin-based pharmaceutical packaging. It effectively reduces both Water Vapor Transmission Rate (WVTR) and Oxygen Transmission Rate (OTR), offering superior protection and extended shelf life for sensitive pharmaceutical products.

Ampacet **ProVital+ GASTOP-FLEX** significantly enhances the barrier performance of mono-material packaging, enabling weight reduction without compromising barrier properties. Fully recyclable and sortable within the polyolefin stream, **ProVital+ GASTOP-FLEX** supports the pharmaceutical packaging industry in its sustainable transition from multi-material to recyclable mono-material solutions.

ProVital+ Germclean

Ampacet ProVital+ Germclean is a medical-grade antibacterial additive technology designed to protect plastic components in healthcare environments by inhibiting the growth of microorganisms. It effectively blocks bacterial proliferation and slows fungal development, helping prevent the formation of harmful biofilms.

ProVital+ LaserMark

The **Ampacet ProVital+ LaserMark** portfolio features specialized masterbatches engineered for high-contrast laser marking using Nd:YAG lasers (1064 nm wavelength). Designed for dark, high-contrast marking on transparent, translucent, white, or light-colored plastic components, **ProVital+ LaserMark** ensures excellent readability and performance. Additionally, the portfolio includes an innovative antimony-free technology.

ProVital+ PROFLOW

Ampacet ProVital+ PROFLOW is a medical-grade PFAS-free and Siloxane-free Polymer Processing Aid (PPA) masterbatch solution designed to replace conventional fluorinated PPA masterbatches used in a wide range of applications.

Perfluoroalkyl and polyfluoroalkyl substances (PFAS) have been associated with potential health risks and are increasingly subject to regulatory restrictions.

Like traditional fluorinated PPAs, **Ampacet ProVital+ PROFLOW** effectively eliminates melt fracture, reduces die build-up, and minimizes downtime while improving throughput.

Disclaimer

Ampacet general disclaimer. Unless otherwise expressly agreed in a written agreement signed by a duly authorized representative of Ampacet, the suitability of our products for any specific intended use by a customer, including in medical applications, is the sole and exclusive responsibility of the customer; Ampacet shall not, under any circumstance, be held liable for any claim related to the specific use or application of its products by a customer in the absence of such agreement. Each user of our products should independently evaluate our product's suitability for their particular use.

Medical devices. Without limiting Ampacet's general disclaimer, Ampacet's products may not be incorporated into medical devices or used for any purposes beyond those specified in the agreement, if any exists, between Ampacet and the customer. The customer or the applicable party that manufactures and/or distributes customer's medical devices on the market shall be solely responsible for ensuring that such medical devices, along with any components used in their manufacturing or packaging, comply with all applicable laws and regulations in the respective jurisdictions of such medical devices' manufacturing, distribution, sale and use.

Regulatory watch. It is customer's responsibility to ensure the Regulatory Watch, i.e. to monitor and implement any change to the intended final application and/or any regulation or law applicable to the final product, and it is customer's responsibility to reassess its product if necessary. On request, Ampacet Representative will be pleased to provide assistance with reassessing customer's product.