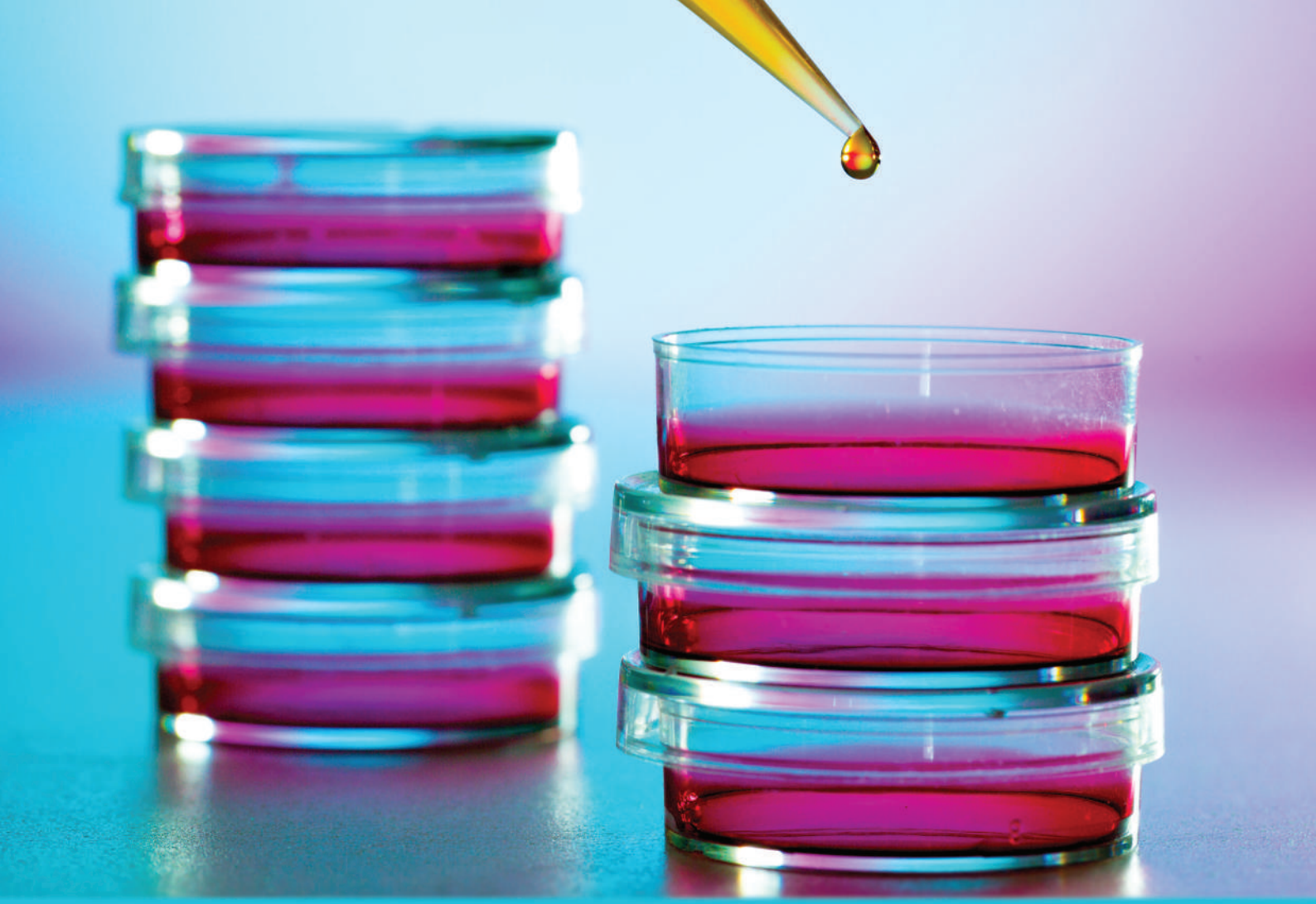
ProVital

Medical Grade Masterbatch Solutions

consistency, conformity & expertise

AMPACET



In today's healthcare environment, medical plastics play a crucial role allowing health care providers to diagnose sickness or disease, treat cases and help to improve patients' quality of life during or after the recovery period.

During the last decade, the size of the European medical plastic market has been significantly expanded by the ageing of the population, dietary changes, development of home healthcare as well as the increased usage of sterilized and disposable accessories for safety or cost reasons.

Plastics have become vital and essential in the medical market as they are replacing conventional materials like metal, ceramic and glass for their mechanical properties, ease of processing, quality, durability, cost-effectiveness, lightweight features and ability to realize complex shapes of products as well as being easy to sterilize.

Complete consistency of performance, traceability and control of raw materials are crucial when manufacturing medical devices, primary packaging or in vitro diagnostics equipment.

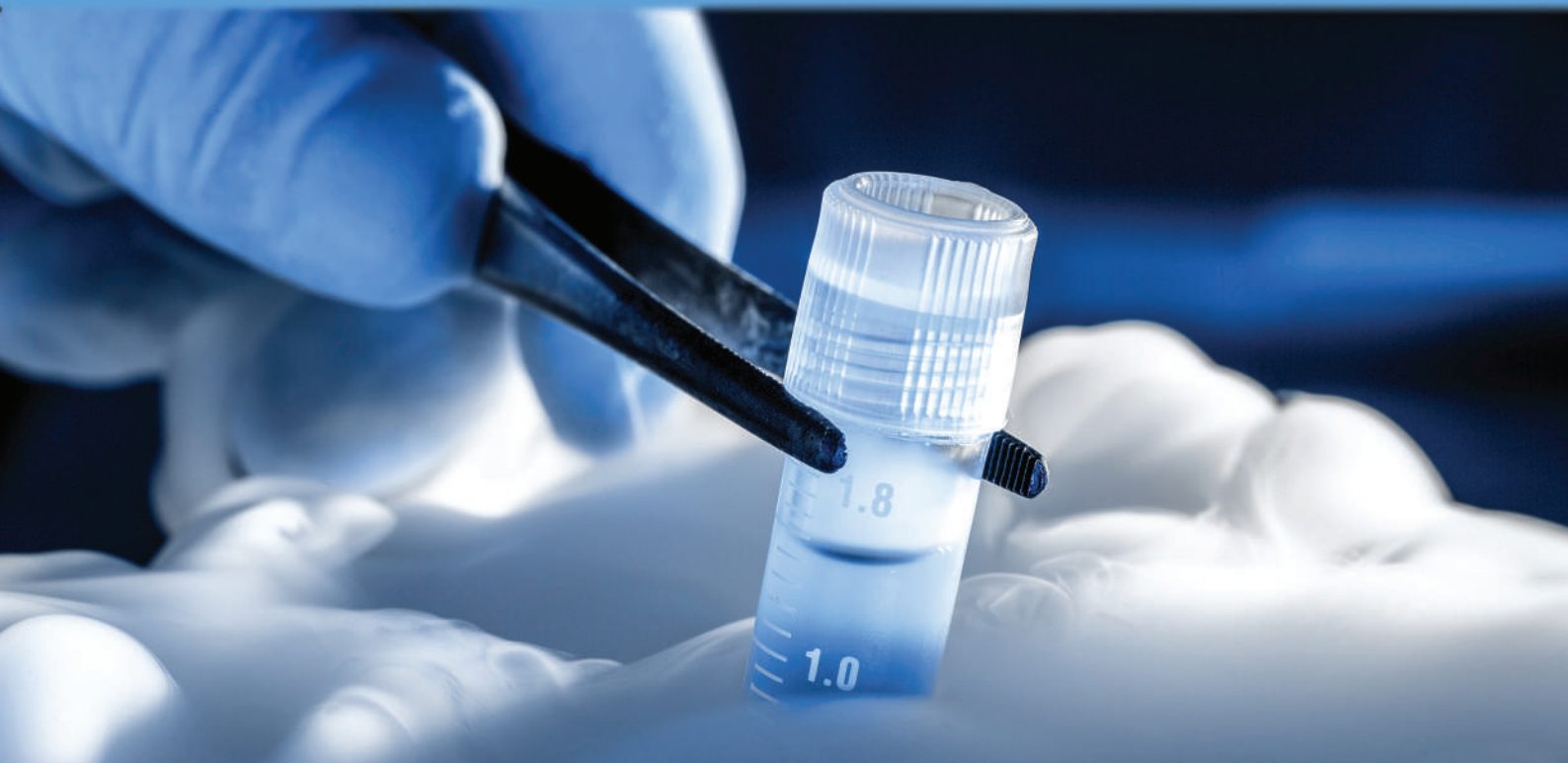
Local governments and international regulating bodies are putting in place new more severe regulations that aim to improve the efficacy and safety of medical technologies.

This complex and strict regulatory environment requires OEMs to select consciously their partners who adhere to stringent quality and performance criteria.

For decades, Ampacet has been a reliable partner who, through building strong long-lasting relationships, helps create a robust and transparent supply chain.

Our unique set of knowledge in the use of materials gathered from multiple industries associated with the know-how of our regulatory experts has led to a portfolio of masterbatch solutions that have been specifically designed for the medical and pharmaceutical markets. Ampacet **ProVital** range meets high industry requirements and is compliant with medical regulations.

Ampacet works with a broad palette of pigments to provide the most aesthetically unique range of "custom" colors and effects. With every step of the product design, our experts will be right there with you to deliver your projects quicker to the market with high quality and consistency.

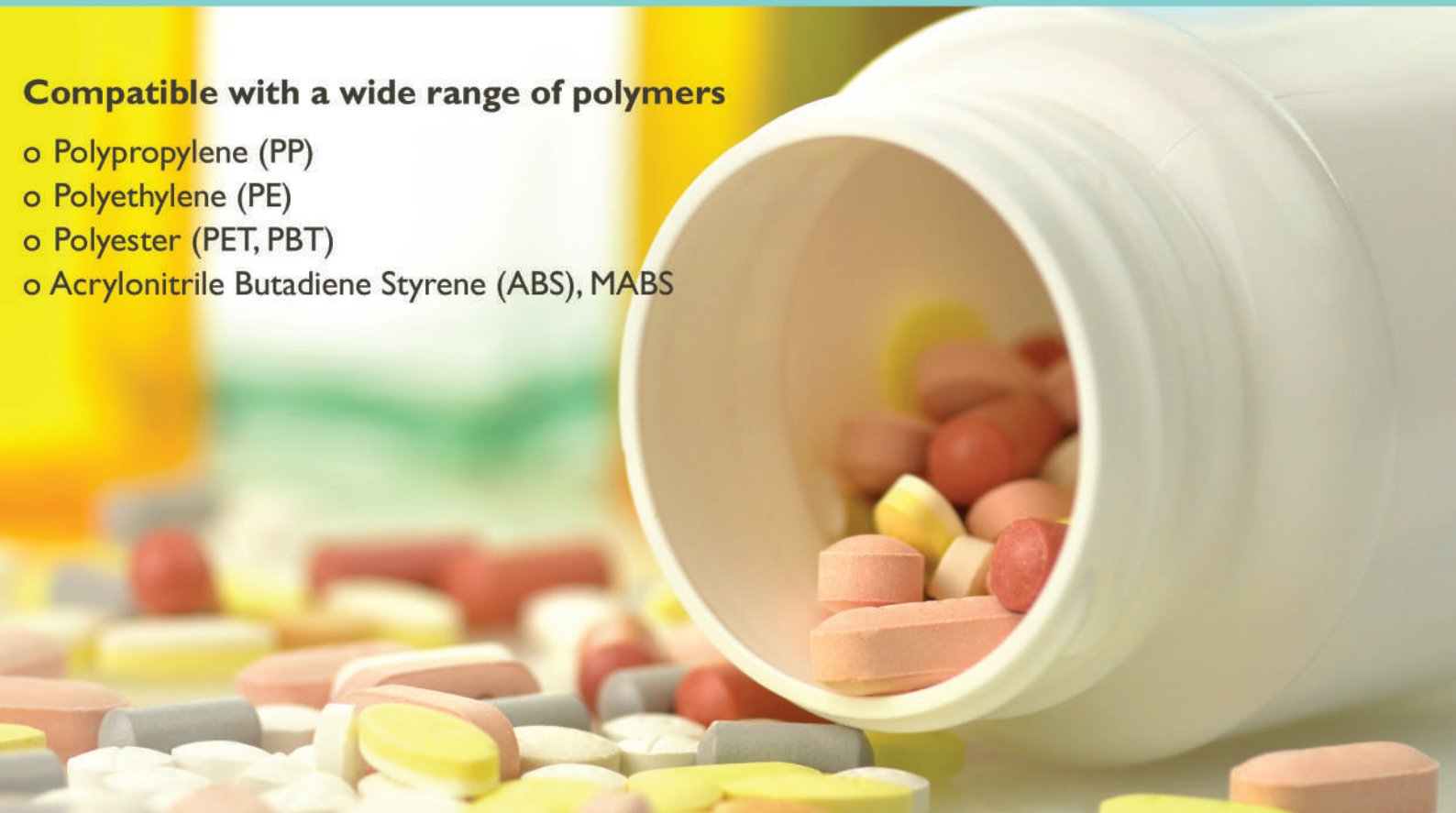


ProVital Range

Standard and tailored masterbatch solutions designed with high quality raw materials to meet performance and safety requirements of the healthcare industry.

ProVital+ Range

Masterbatch solutions formulated with pre-tested raw materials to support our customers to meet ISO 10993 biocompatibility requirements and European Pharmacopeia standard. This product range is produced under stringent production controls.



Compatible with a wide range of polymers

- Polypropylene (PP)
- Polyethylene (PE)
- Polyester (PET, PBT)
- Acrylonitrile Butadiene Styrene (ABS), MABS

	ProVital+ Medical Grade - EM	ProVital Healthcare Grade - EH
Raw Materials	• Selected high quality raw materials • No change policy for raw materials at CAS and trade name level • Control of incoming raw materials • Medical grade polymers as carrier	• Selected high quality raw materials • No change policy for raw materials at CAS level
Manufacturing Process	• No change in the process parameters window • Sampling produced under serial conditions as per agreement • Recording of process parameters for each batch • Full traceability of raw materials, intermediates and finished goods • Reinforced cleaning procedures • Production under HACCP principles	• Full traceability of raw materials, intermediates and finished goods • Reinforced cleaning procedures • No change of production lines if specified
Consistency Assessment	• QC Tests • No change in raw materials and process parameters	• QC Tests • No change in raw materials
Security of supply	• Yes	• No
Change Management	• Notification of change	• Notification of change limited to raw materials at CAS and trade name level
Information & Documentation	• Full documentation support • Drug Masterfile DMF • Formulated with raw materials pre-tested to EU Pharmacopeia and Biocompatibility	• Full documentation support • Drug Masterfile DMF
Applications	Designed for medical applications • Primary packaging • Medical Devices • In vitro Diagnostics	Designed for applications requiring quality standard beyond normal food contact

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Plastics Reimagined™

Disclaimer

1. Ampacet general disclaimer. Unless otherwise expressly agreed in a written agreement signed by duly authorized representative of Ampacet, the choice of our products for any specific intended use is the sole and exclusive responsibility of the customer; Ampacet shall not, under no circumstances, be held liable for any specific use nor application of its products by a customer in the absence of such agreement.

2. Medical devices. More particularly and without prejudice to Ampacet's general disclaimer, Ampacet products are not intended for use, nor to be incorporated in the manufacture of medical devices which are categorized or classified as:

   i. United States' Food and Drug Administration Class III, Canadian Classes III and IV and European Union Classes IIb and III or any equivalent within another country's regulatory classification.

   ii. "Invasive devices", devices for "Long Term" (i.e., in principle longer than 30 days) use or devices involved in a "Vital physiological process" as defined by the International Medical Device Regulators Forum - IMDRF (formerly Global Harmonization Task Force) as well as by the applicable regulations on medical devices.

3. The natural or legal person in charge of the placing on the market, making available on the market or putting into service of medical devices and/or their accessories shall be the sole and exclusive responsible to ensure compliance of such devices or accessories with applicable laws and regulations. This also includes compliance in relation to any material or component which is used for their manufacture or the manufacture of their packaging.

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Version: September 2021