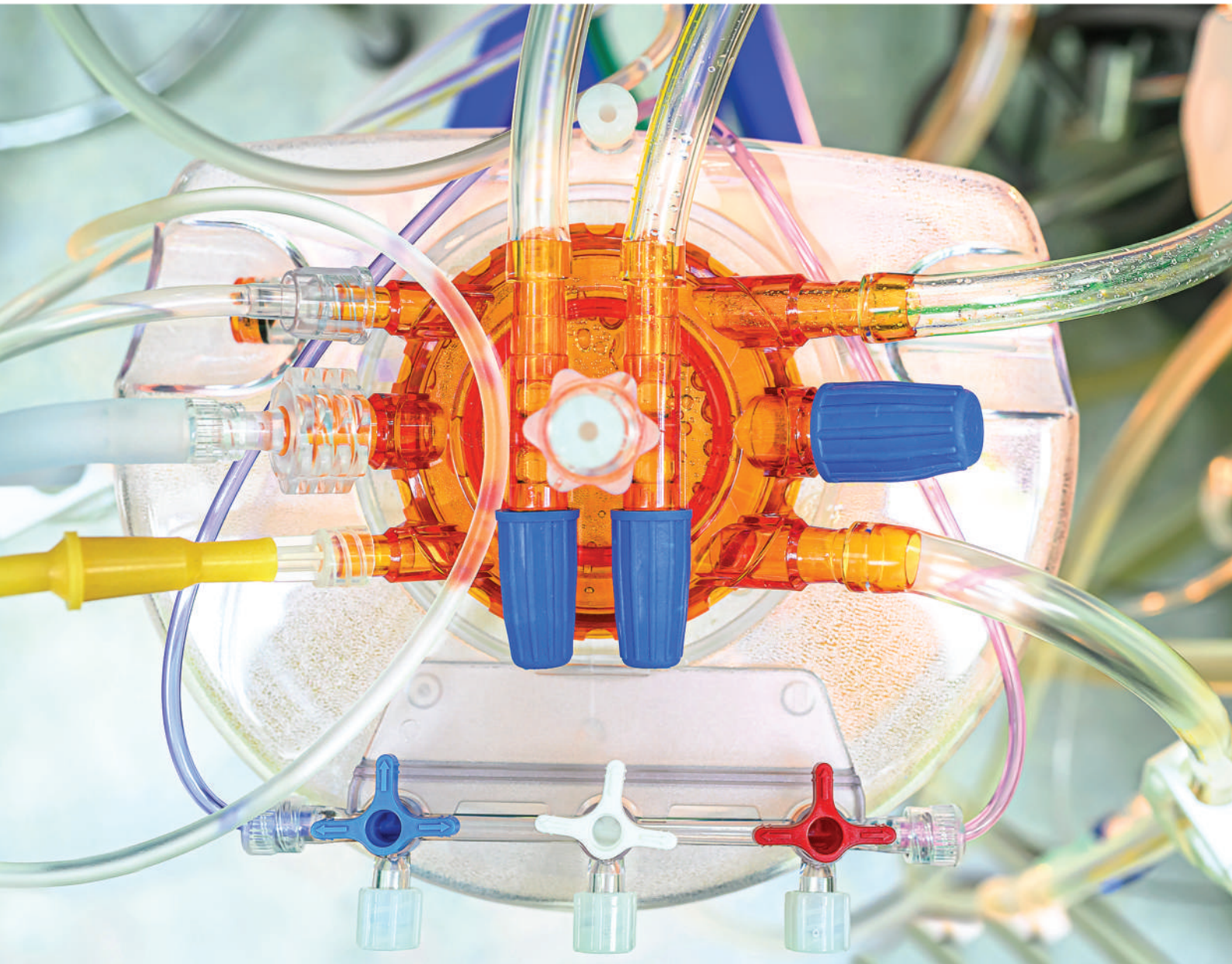


# ProVital+



Medical Grade Color Masterbatch Solutions

consistency, conformity & expertise

AMPACET

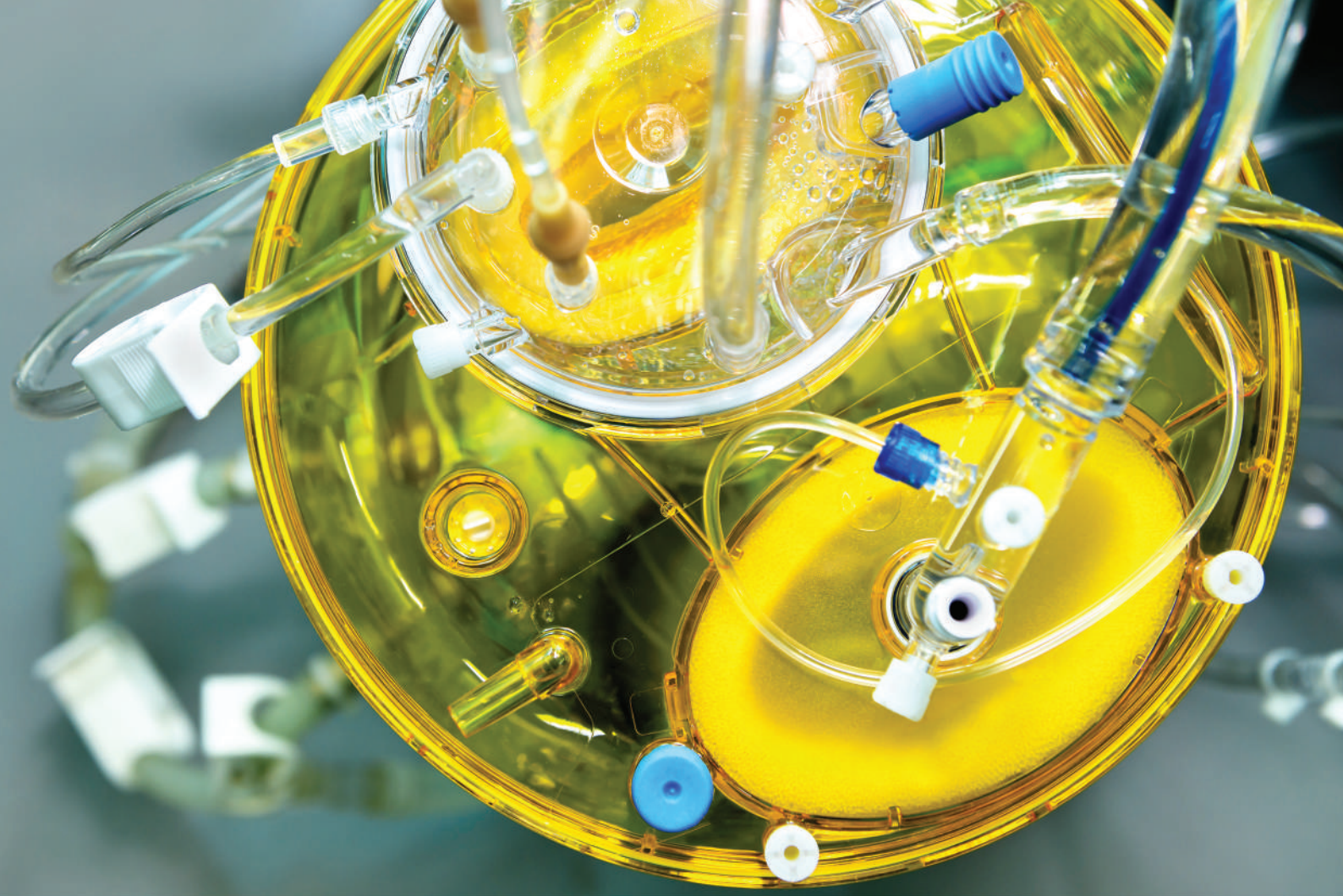
**Selection of the appropriate raw material** is a fundamental step of the product design process in the healthcare area whether it is for pharmaceutical packaging, medical devices or in-vitro diagnostics equipment.

**Color selection** is another important element of the product design. Colors can be used as an opacifier to protect the medication, as a color-coding for rapid identification, for branding or aesthetic appeal purpose.



**Ampacet ProVital +**  
Standard & Tailor-made  
Medical Grade Colors





An extensive test program is necessary to ensure that the selected material meets all the performance criteria and comply with the increasingly stringent regulations.

The choice of the **appropriate material and color** at the early stage of the product design helps brand owners to minimize number of tests, development costs and reduce time to market.





# ProVital+ Color Solutions

designed for coloration of medical devices, in-vitro diagnostics equipment and pharmaceutical packaging

formulated with raw materials pre-tested for Biocompatibility under ISO 10993

high level of quality, reliability & consistency

strict no-change policy of raw materials at CAS and trade name level

color matching service

consistent manufacturing process parameters

production under HACCP principles to minimize risks of cross contamination



# ProVital+ Standard Colors



In addition to the standard polyolefin color range, custom colors can be designed with the pre-tested pigments and different polymers on-request.

To support customers in product design, Ampacet offers full regulatory documentation for ProVital+ product range:

- Regulatory Status
- Drug Master File
- Safety Datasheet
- Technical Datasheet





# AMPACET

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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