

ALCOM[®] MED – MEDICAL

Enhancing Life



ALCOM[®] MED addresses the strict requirements of a sensitive industry by offering customized compounds for the use in medical, pharmaceutical or diagnostic applications.

Healthcare applications require the highest level of sensitivity and profound industry knowledge, which is perfectly reflected in the ALCOM[®] MED product range. Complemented by our technical and regulatory expertise and customized service packages, ALBIS provides compound solutions for a wide range of applications such as medical devices, pharmaceutical packaging and diagnostic lab equipment as well as bioscience applications.

Depending on the exact requirements needed for a certain application, combined with customer specific requests such as polymer, color, filler or additive packages, ALBIS can offer niche products for the healthcare industry based on a variety of polymers which not only convince by their functionality but also by their attractive and useful appearance. ALBIS would also be pleased to support you by developing individual compound solutions meeting your specific requirements.

ALBIS' strict quality and risk management procedures as well as a comprehensive service package complement the products themselves. On request and dependent on the material composition required, the service package can optionally include compliance with biocompatibility standards such as the relevant chapters of ISO 10993 as well as USP class VI and European Pharmacopeia. Individual agreements on Notifications of Change or supply safety are also available. Furthermore, all ALCOM[®] MED compounds are produced according to GMP (Good Manufacturing Practice according to regulation EC 2023/2006) procedures, which guarantee a continuous high quality level.

ALCOM[®] MED: advantages at a glance

- Tailor made compounds regarding polymer, color, filler & additive packages
- Food contact statements (EU/FDA) available
- Manufacturing according to GMP
- Supply safety through individual agreements
- Notification of change (NoC) through individual agreements
- Statements, testing and/or certification against relevant chapters of ISO 10993 and USP class VI such as EP (optional)
- Full traceability

Polymer	Material name	Color / Characteristics	GMP* Production Process	Food Contact LM-EU & FDA	ISO 10993 for Base Polymer	USP class VI for Base Polymer	Sample applications
PP	ALCOM® MED PP 1000 16078	unfilled, natural and colored	✓	✓	✓	✓	Housings for injection pens and inhalers, diagnostic devices, labware, syringes, dialysis equipment, containers, caps and closures
	ALCOM® MED PP 2020 16108	20% glass fibers, natural and colored	✓	✓	✓	✓	
PE	ALCOM® MED PE-LD FC 1000 16079	unfilled, natural and colored	✓	✓	- *2	✓	Caps and closures, pharmaceutical packaging, diagnostic applications, tube shoulders, syringe barrels
PS	ALCOM® MED PS 1000 16105	unfilled, natural and colored	✓	✓	✓	✓	Labware, packaging, housings, diagnostic devices, petri-dishes, roller-clamps
	ALCOM® MED PS 1000 16106	unfilled, natural and colored	✓	✓	✓	✓	

* = Good Manufacturing Practice (GMP) according to GMP regulation EC 2023/2006

*2 = Raw material test not performed

Additional products and information are available on request.

Healthcare uses: the supply of any product by ALBIS for any medical, pharmaceutical or diagnostic application is conditional to an assessment by ALBIS in terms of compliance with ALBIS' internal risk management policy – even for products which are in general designated for use in Healthcare applications.

Important: irrespective of product type or designation, ALBIS does not recommend or support the use of any products it supplies which fall into the following medical, pharmaceutical or diagnostic application categories:

- Medical devices categorized as risk class III according to Medical Device Regulation (MDR) or risk class 3 FDA
- any bodily implant application for greater than 30 days
- any critical component in any medical device that supports or sustains human life.

At all times, our standard terms and conditions of sale apply.

HEAD OFFICE

ALBIS PLASTIC GmbH
Mühlenhagen 35 · 20539 Hamburg
Tel.: +49 40 7 81 05-0 · Fax: +49 40 7 81 05-361
info@albis.com · www.albis.com

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