

# POLYMiX

AT THE HEART OF MATERIALS

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## POLYMiX

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# PREVENTING, DIAGNOSING, HEALING

*French leader in the distribution of technical polymers, POLYMIX is more than ever positioned as an innovation finder. For 40 years, POLYMIX has displayed a know-how and a multi-skill in the commercialization of thermoplastic materials.*

Preventing, diagnosing and healing are the key focus of health actors, hospitals and laboratories.

POLYMIX supports you in your projects, with a large and diversified range as well as a recognized expertise in medical matters. Our materials meet the requirements of medical and diagnostics devices, pharmaceutical and medical packaging. We support you from the identification of materials to their homologation.

POLYMIX partners are **ISO13485** certified and offer materials in compliance with the pharmacopea regulatories : **ISO10993, USP6, EP3.1, USP661, and FDA Drug Master File.**

In addition, the inherent properties of thermoplastics offer many solutions for your projects:

- ☑ Transparency or opacity
- ☑ Physical and mechanical properties
- ☑ Hardness and flexibility
- ☑ Modulus
- ☑ Density
- ☑ Thermal properties
- ☑ Tribological properties
- ☑ Improved chemical resistance
- ☑ Lipid resistance
- ☑ Resistance to tearing and percability, breakability of packaging
- ☑ **Sustainable materials**



## STERILIZATIONS AND DESINFECTIONS

Concerned about the quality of the medical devices after their sterilization, **POLYMIX** has the expertise and offers tailored solutions according to the different processes intended to **single use and multi-use medical devices:**

- ☑ Ethylene oxide
- ☑ Irradiation : gamma, Xray, E-beam
- ☑ Autoclave
- ☑ Repeated disinfections (solvents)
- ☑ Decontamination : UV-C and antimicrobial solutions



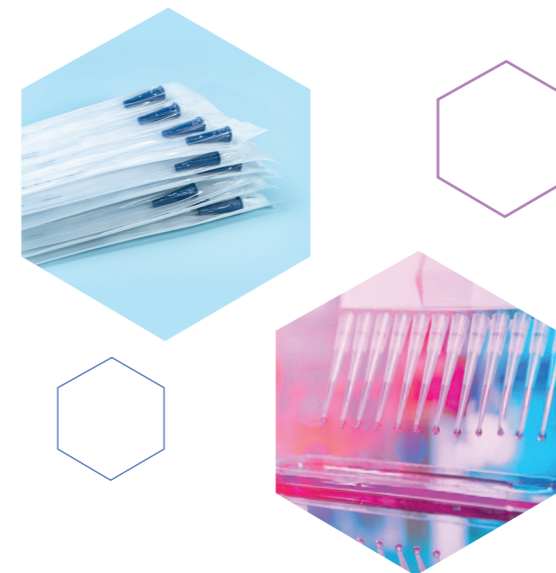
# ARE THE KEY FOCUS OF THE HEALTH ACTORS, HOSPITALS AND LABORATORIES

## DIAGNOSTIC DEVICES PIPETS, TUBES, CONTAINERS

- ☑ Biocompatibility
- ☑ High transparency

## ELECTRONIC AND CONNECTED MEDICAL DEVICES

- ☑ Biocompatibility
- ☑ Improved chemical resistance
- ☑ Aesthetics
- ☑ Halogen free UL94 V0 ignifugation
- ☑ Radio-frequencies and electrostatic discharges protection



## FLEXIBLE AND RIGID MEDICAL PACKAGING

- ☑ Biocompatibility
- ☑ Transparency
- ☑ Barrier effect
- ☑ Resistance to tearing, piercing and breakability
- ☑ Impact resistance including cold impact

## SINGLE-USE MEDICAL DEVICES

- ☑ Biocompatibility
- ☑ Materials for functional components



## SURGICAL DEVICES

- ☑ Biocompatibility
- ☑ Metal replacement
- ☑ Aesthetics
- ☑ Increased autoclave capacity (< 2 500 cycles at 134°)

## SUSTAINABLE SOLUTIONS

Bio-based and recycled materials in the respect of the biocompatibility





			MEDICAL CERTIFICATIONS		STERILIZATION			CHEMICAL RESISTANCE	TRANSPARENT	
			ISO10993	USP6	GAS	IRRADIATION	AUTOCLAVE			
					ETO	GAMMA / E-BEAM / X-RAY	134°C			
 	HPP	PP	●	●	●●●	●●○	121°C - 1 cycle	●●●	●	
	HPR	PP copo	●	●	●●●	●●○	121°C - 1 cycle	●●●	●	
	HPP-RMD / HPR-RMD Improved irradiation	PP / PP copo	●	●	●●●	●●●	121°C - 1 cycle	●●●	●	
	HLD	LDPE	●	●	●●●	●●○	○	●●●	●	
	HHD	HDPE	●	●	●●●	●●○	121°C - 1 cycle	●●●	●	
	HVA	EVA copo	●	●	●●●	●●○	○	●●●	●	
<b>SUSTAINABLE</b>	Sustainable and biobased range available for PP, PE and EVA.									
	HH104 MED	PS	○	●	●●●	●●○	○	●●○	●	
	6110MED - 6420MED	HIPS	○	●	●●●	●●○	○	●●○	○	
	CET®	SMMA	○	●	●●●	●●○	○	●●○	●	
	KEPITAL™ MX	POM	●	●	●●●	●●○	< 50 cycles	●●●	○	
	RILSAN®	PA11	○	○	●●●	●●○	< 100 cycles	●●●	○	
	RILSAN® CLEAR	PA11 transparent	○	○	●●●	●●○	< 100 cycles	●●○	●	
	PEBAX®	PEBA	○	○	●●●	●●○	< 25 cycles	●●●	○	
<b>SUSTAINABLE</b>	Sustainable and biobased range from renewable castor oil available.									
	CYCOLAC™ HMG	ABS	●	●	●●●	●●○	○	●●○	○	
	VALOX™ HX	PBT	●	●	●●●	●●●	○	●●●	○	
	LEXAN™ HP	PC	●	●	●●●	●●○	< 10 cycles	●●○	●	
	LEXAN™ HPS Improved irradiation	PC	●	●	●●●	●●●	< 10 cycles	●●○	●	
	<b>SUSTAINABLE</b>	Sustainable range coming from renewable pine oil available for PC.								
	CYCOLOY™ HC	PC/ABS	●	●	●●●	●●○	○	●●○	○	
	XYLEX™ HX	PC/PET	●	●	●●●	●●●	○	●●○	●	
XENOY™ HX	PC/PBT	●	●	●●●	●●●	○	●●○	○		

● Yes ○ No ● On request ●●○: limited ●●●: good ●●●: excellent



MEDICAL CERTIFICATIONS		STERILIZATION			CHEMICAL RESISTANCE	TRANSPARENT
		GAS	IRRADIATION	AUTOCLAVE		

ISO10993	USP6	ETO	GAMMA / E-BEAM / X-RAY	134°C		
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<p>سابك sabic Specialties</p>	LEXAN™ HPX	PC copo	●	●	●●●	●●○	< 100 cycles	●○○	●
	LEXAN™ HPH	PC copo	●	●	●●●	●●○	< 300 cycles	●○○	●
	ELCRES™ CRX	PC copo	●	●	●●●	●●○	< 10 cycles	●●●	●
	ELCRES™ CRX	PC copo/PBT	●	●	●●●	●●●	○	●●●	○
	ELCRES™ CYCOLOY™ CX2244ME	PC copo/ABS	●	●	●●●	●●○	○	●●●	○
	NORYL™ HN	PPO	●	●	●●●	●●●	< 2 500 cycles	●●●	○
	ULTEM® HU	PEI	●	●	●●●	●●●	< 1 000 cycles	●●●	●
<b>SUSTAINABLE</b>	Sustainable range coming from renewable pine oil available for PC copo, PPO and PEI based materials.								
<p>优巨新材 YOUJU XIN CAI</p>	PARYLS®	PPSU	●	○	●●●	●●○	< 500 cycles	●●●	●
<p>GHARDA PLASTICS A BUSINESS DIVISION OF GHARDA CHEMICALS LIMITED</p>	G-PAEK™ 1200G	PEK	●	●	●●●	●●●	< 1500 cycles	●●●	○
<p>GRECO</p>	ISOTHANE® SERIE 5000	TPU ether	○	●	●●●	●○○	○	●●○	●
<p>elastron ENGINEERING LIFE</p>	ELASTRON	TPE	●	●	●●●	●	●	●●●	○
<p>PREMIX</p>	PRE-ELEC®	Conductive compounds	○	○	●●●	●	○	○	○
<p>CHIMEI</p>	POLYLAC® PA757F	ABS	○	●	●●●	●●○	○	●○○	○
	POLYLAC® 704LRP	ABS	●	○	●●●	●●○	○	●○○	○
	POLYLAC® PA758	MABS	○	●	●●●	●●○	○	●○○	●
	POLYLAC® PA703TRP	MABS	●	○	●●●	●●○	○	●○○	●
	KIBITON® PB-5903	SBC	○	●	●●●	●○○	○	●●○	●

● Yes ○ No ● On request ●○○: limited ●●○: good ●●●: excellent

AMP

ADDITIONAL RANGE

<p>PurgeX™ Purging Compounds</p>	<p><b>Purging compound</b> for colors and resins change. Effectively removes contamination. Fast action and non-abrasive. Easily removed.</p>
	<p><b>Permanent antistatic materials</b> dedicated to the medical environment.</p>



**NOTE**  
ISO 10993 - The ISO 10993, regulated by the International Organization for Standardization (ISO), is a standard series for the biological evaluation of medical devices. The aim of the standard is to evaluate the biological assessment regarding the biocompatibility of the materials with the human body.  
Important parts :  
- ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity  
- ISO 10993-11:2008 Biological evaluation of medical devices Part 11: Tests for systemic toxicity  
DMF - A Drug Master File (DMF) is a confidential, detailed document about active substances contained in the medical product. It is submitted from manufacturers to the U.S. Food and Drug Administration (FDA). A DMF contains the chemistry, manufacturing and controls of a component of a drug product. There is no legal obligation to create a DMF and to submit it to the authorities.  
USP - The United States Pharmacopeia (USP) includes standards to guarantee the quality and purity of medicines and health technologies worldwide. It covers tests relating to the biological reactivity of elastomers, plastics and other polymer materials with direct or indirect customer contact. USP Class VI is the most stringent test and accepted in the sector.  
The AMP-POLYMiX Group authorises the use of materials for class I and II medical devices. For class III and/or implantable medical devices (short term, long term and permanent), the use of a material must be subject to a prior negotiated agreement between the different parties.  
**DISCLAIMER**  
Any information given on the chemical and physical characteristics of products, including technical advice on applications whether verbally, in writing or by testing the product, is given to the best of our knowledge. It does not exempt the buyer from carrying out his own investigations and tests in order to ascertain the products' specific suitability for the purpose intended. The buyer is solely responsible for the application, utilization and processing of the products and must observe the laws and government regulations and the consequential rights of any third party. At all times our Conditions of Sale apply. Please contact us to inquire availability per represented countries.  
AMP-POLYMiX Group doesn't authorize the use of materials for class III material devices.