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Member of **POLYMIX-AMP** Group
FRANCE · BENELUX · MAGHREB · IBERIA · SLOVENIA · CROATIA · ROMANIA

AU COEUR DE LA MATIÈRE

OUR ETP RANGE FOR HEALTHCARE APPLICATIONS

polymix

			CERTIFICATIONS			STERILISATION				LIPID RESISTANT	TRANSPARENT	BPA FREE
			MEDICAL			IRRADIATION		GAS	AUTOCLAVE			
			USP CLASS VI	ISO 10993	DMF	E-BEAM	GAMMA	ETO	IN °C			
SABIC	Cycoloy HG®	ABS/PC	●	●	○	●	●	●	○	○	○	○
	Cycolac HMG®	ABS	●	●	◑	●	●	●	○	○	○	●
	Noryl HN®	PPO	●	●	○	●	●	●	134	●	○	●
	Valox HX®	PBT	●	●	○	●	●	●	134	●	○	◑
	Lexan HP®	PC	●	●	○	●	●	●	121-134	●	●	○
	Xylex HX®	PC BLEND	●	●	○	●	●	●	○	●	●	○
	Xenoy HX®	PC BLEND	●	●	○	●	●	●	○	○	○	○
	Ultem HU®	PEI	●	●	○	●	●	●	134	●	●	○
UBE	Paryl®	PPSU	○	●	○	○	○	○	134	○	○	●
KRAIBURG TPE	Thermolast M®	SEBS	●	●	●	●	●	●	134	●	○	●
KEP for a better future	Kepital MX®	POM	●	●	●	○	○	●	◑	○	○	●
Resirene	CET 100®	SMMA	●	○	○	○	●	●	○	●	90%	●
	CET 200®	SMMA	●	○	○	○	●	●	○	●	90%	●
LG Chem	TR580®-TR558A®-TR557®	MABS	●	●	○	○	MAX 25kGy	1-5 CYCLES	○	●	HAZE 1.8-2.3	●
	TR556®	MABS	●	○	○	○	MAX 25kGy	1-5 CYCLES	○	●	OPAQUE	●
	HI121®-HI121H®-HF380®	GP ABS	●	○	○	○	MAX 25kGy	1-5 CYCLES	○	●	OPAQUE	●
GGRECO	Isothane® 3085AU-EJ®	TPU	○	●	○	○	●	◑	○	○	●	●
	Isothane® 5080A-85A-90A	TPU	●	○	○	○	●	◑	○	○	●	●
K-RESIN	AMP											
	K resin®	SBC	●	●	●	○	●	●	○	○	●	●

AMP ADDITIONAL RANGE

GABRIEL-CHEMIE GROUP PLASTIKA KRITIS S.A.	**Masterbach** white and various colors **Additives** antimicrobial, laser marking, slip .... FDA certified grades For technical and commodities resins	Purgex Purging Compounds	**Purging compound** for colors and resins change Effectively removes contamination Fast action and non-abrasive Easily removed FDA certified grades

● Oui ○ Non ◑ Sur demande

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 10993-11:2006 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.

DISCLAIMER

Please contact us to inquire availablity per represented countries.