

# INEOS

## Olefins & Polymers Europe

Your partner in pharmaceutical

# BLOW FILL SEAL

**Proven** Solutions  
for medical and  
pharmaceutical packaging

[www.ineospolyolefins.com](http://www.ineospolyolefins.com)

**INEOS Olefins & Polymers Europe** is a market leading polyolefin producer, operating from a uniquely broad technology base. With a highly experienced sales and technical service team as well as extensive Research and Development facilities we are committed to developing and manufacturing specific product solutions for high demanding markets such as medical devices and pharmaceutical packaging. In a market requiring long and complex homologation protocols, Eltex® MED has a proven track record in meeting the needs of high-value packaging applications for medical & pharmaceutical products:

- Additive-free resins guaranteeing optimised resin purity and quality consistency
- Chemical inertia, compliance to regulations
- Suitable for many converting processes, offering fast production cycles and design versatility
- Preserving the quality of the most sensitive products
- Ability to be sterilised including autoclaving, EtO and gamma-radiation (up to 35KGy)
- Offering much more than a product, offering you solutions



## BLOW FILL SEAL

### *Pharmaceutical applications – what Eltex® Med provides*

#### Product availability/change control

- Continuity of supply and formulation (2 years)
- Notice of changes (2 years)

#### Certification and Regulation

- European Pharmacopoeia composition compliance to Polyolefin related monographs: 3.1.4, 3.1.6
- United States Pharmacopoeia USP class VI
- Drug Master File nr. 21252 & 20554
- Formula disclosure under secrecy agreement

#### Tested Grades

- EUP Full Testing 3.1.4 & 3.1.6
- USP Class VI Tested

#### Customised support

- Technical Support specific to Eltex® MED
- Certificates online, Eltex® MED personalised access

#### Control and logistic

- Maximised batch purity
- Consistency batch-to-batch
- Traceability (documentation and QC samples)
- Inside storage/enhanced clean logistics: manufacturing to unloading

# ELTEX® MED PRODUCT RANGE FOR BFS

*A wide range of regularly tested Polymers*

## LDPE Eltex MED Range

Grades manufactured at our Norwegian facility in Bamble, certified ISO 9001 & 14001, on a totally additive-free production line and dedicated logistics/packaging area, enabling efficient risk management by minimising and eliminating the occurrence of cross-contamination.

	MFI <i>g/10min</i>	Density <i>kg/m<sup>3</sup></i>	Main Properties	Applications
Test Method	ISO 1133	ISO 1872		
PH22D630	0.3	922	Outstanding flexibility	BFS (SVP bottles & ampoules)
PH27D630	0.3	927	Steam autoclave treatment up to 110 °C	BFS (SVP bottles & ampoules)
PH30D630	0.3	930	Steam autoclave treatment above 110 °C	BFS (MVP & LVP bottles)
PH23H630	2	923	High fluidity requirements	Unidose ampoules

## PP Eltex® MED Range

Grades manufactured at our Lavéra facility in the South of France certified ISO 9001 & 14001

	MFI <i>g/10min</i>	Flex Mod 23 °C <i>Mpa ISO 178</i>	Main Properties	Applications
Test Method	ISO 1133	ISO 1872		
200-MG02	1.8	900	Good optical properties. Can be steam sterilised to 121 °C. Easy processing.	BFS (bottles & ampoules)

## ELTEX<sup>®</sup> MED

### Advantages & Support

- Manufacturing in compliance with food-GMP's requirements & guidelines
- Longer transition purge and/or appropriate placement into the product wheel
- Narrowest manufacturing specifications
- Mention of Date of Manufacture onto CoA's
- Advanced CoA upon agreement including full European Pharmacopeia (3.1.4 for LDPE/3.1.6 for PP) testing on batch delivered
- Periodic microbiological assessment on granules and/or pelletisation water
- Batch archive-sample retained for min. 3 years
- FTIR spectrum fingerprint archived on each batch
- EuP & USP testing periodically performed

INEOS is one of the world's largest chemical companies. Founded in 1998, the company employs 15,000 people and has turnover of around 40 billion US Dollars.

[www.ineos.com](http://www.ineos.com)

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