## PRODUCT DATA SHEET

ELAREM™ Ultimate-FD PLUS





# ELAREM™ Ultimate-FD PLUS

**GMP Grade** 

+
GAMMA IRRADIATED FOR
ADDITIONAL SAFETY

GMP GRADE HPL FOR CELL MANUFACTURING

CONSISTENT CELL
CULTURE PERFORMANCE

+ ENHANCED TRACEABILITY ELAREM™ Ultimate-FD PLUS is a gamma irradiated, fibrinogen-depleted and heparin-free Human Platelet Lysate of EU origin.

The xeno-free cell culture supplement is especially suited for cell manufacturing applications requiring proven viral reduction for potential use in clinical trials.

ELAREM™ Ultimate-FD PLUS is manufactured, tested and released in compliance with the relevant GMP guidelines. The manufacturing process for the product is patented.

By ensuring an EU-based raw material supply chain, we provide a traceability over 30 years back to blood component.

# PRODUCT DATA SHEET

ELAREM™ Ultimate-FD PLUS

PRODUCT	APPLICATION	SIZE	HEPARIN REQUIRED	STORAGE	SHELF LIFE*	ORDER NUMBER
ELAREM™ Ultimate-FD PLUS	GMP Grade	50 mL	No	-40°C to -20°C	1 year	UL30621
ELAREM™ Ultimate-FD PLUS	GMP Grade	500 mL	No	-40°C to -20°C	1 year	UL31021

<sup>\*</sup> Shelf life duration is determined from date of manufacture, continuously stored frozen in original bottle.

### **BACKGROUND**

As a xeno-free cell culture supplement, **ELAREM™ Ultimate-FD PLUS** supports the efficient and safe *in vitro* expansion of various primary cells and cell lines.

**ELAREM™ Ultimate-FD PLUS** is manufactured, tested and released in compliance with the relevant GMP guidelines. The manufacturing process for the product is patented.

While all ELAREM™ Human Platelet Lysates are manufactured from screened platelet units, ELAREM™ Ultimate-FD PLUS ensures additional safety through a validated gamma irradiation process. By conducting a viral clearance study, we demonstrated viral reduction for the tested viruses while preserving cell culture performance. As a final manufacturing step, the product undergoes gamma irradiation at a dose range of 38-55 kGy.

#### **INTENDED USE**

**ELAREM™** Ultimate-FD PLUS - GMP Grade is for manufacturing use only. The product is not intended for any animal, human or therapeutic use.

For safety precautions, please see appropriate Safety Data Sheet (SDS).

#### **STERILITY**

ELAREM™ Ultimate-FD PLUS is aseptically processed. Microbial cultures tested negative. Quality control testing is carried out in a certified test laboratory.

#### TRACEABILITY AND PRECAUTIONS

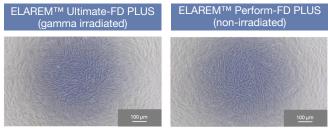
**ELAREM™ Ultimate-FD PLUS** is manufactured from platelet units obtained from healthy donors following European guidelines.

## PRODUCT SUPPORT

If you have any questions, please feel free to contact us by phone at +49 241 957 19-100 or by e-mail at info@pl-bioscience.com.

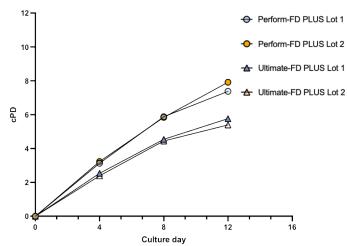
#### PRODUCT DATA

Morphology of hASCs cultured in irradiated vs. non-irradiated Human Platelet Lysate (10% v/v)



QC data show preserved cell density and viability after gamma irradiation of Human Platelet Lysate.

Cumulative Population Doublings (cPD) of hASCs in irradiated vs. non-irradiated Human Platelet Lysate (10% v/v)



Long-term culture results show sustained cell proliferation with irradiated Human Platelet Lysate.

**SEND US YOUR REQUEST** 

www.pl-bioscience.com/contact

