

**SINGLE  
USE  
SUPPORT.** 

PIONEERING BIOPHARMA



# IRIS Single-Use Bag

Primary packaging for your  
highly valued product

*100 % protection – 0 % product loss,  
for the highest storage density*

# IRIS Single-Use Bag

**Protect and freeze your bulk drug substance to ensure 0 % product loss during freezing, storage and transportation!**

Our proven IRIS single-use bag provides reliable and secure primary packaging for your product needs.

Available in a range of sizes and constructed with multilayer polyethylene (PE) films, IRIS bags are fully qualified, validated, and adaptable to meet individual customer requirements.



## Facts

- Available with highly protective, low-permeability, inert PE multilayer film
- Suitable for temperatures between -85°C and +55°C
- Custom assemblies with tubing & connector of choice available
- Irradiation sterilization based on international biopharmaceutical standards
- Compatible with Single Use Support manifolds for a fully closed sterile ready-to-use system
- Fast lead times of down to 10-12 weeks based on complexity

## Bag Sizes

To meet your individual needs IRIS single-use bags are available in different sizes from 20mL to 10L:

20mL, 50mL, 100mL, 250mL,  
500mL, 1L, 2L, 5L, 10L



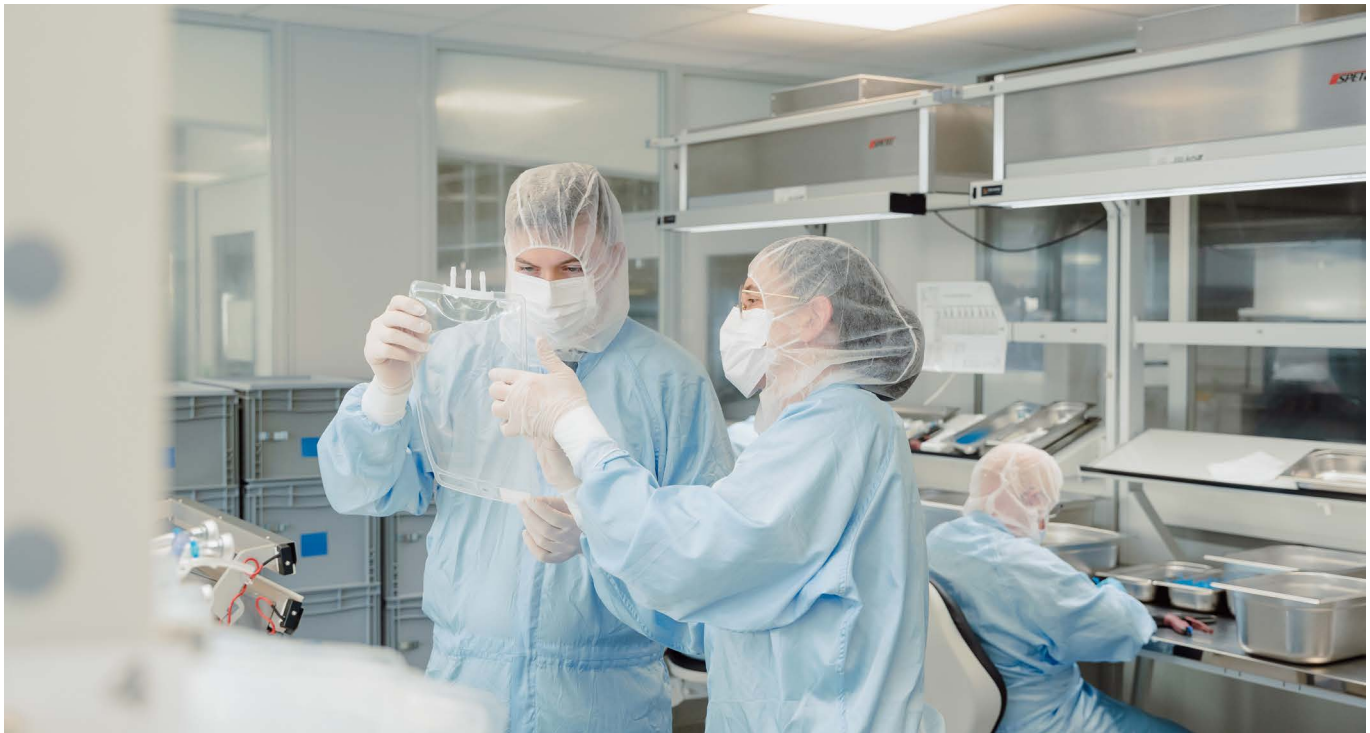
# Validation Regulatory

## PHARMACOPOEIA COMPLIANCE AND BIOCOMPATIBILITY\*

ISO 10993-4 Hemolysis
ISO 10993-5 Cytotoxicity
ISO 10993-6 Implantation test
ISO 10993-10 Irritation and Sensitization tests
ISO 10993-11 Acute Systemic Toxicity test
USP <85> Bacterial Endotoxins - LAL test
USP <87> Biological Reactivity Test in Vitro
USP <88> Biological reactivity testing, in vivo, class VI
USP <661.1> Polyethylene; Physiochemical Tests, Extractable Metals, Plastic Additives
USP <788> Particulate Matter in Injections
European Pharmacopoeia tests, Ch. 3.1.5.

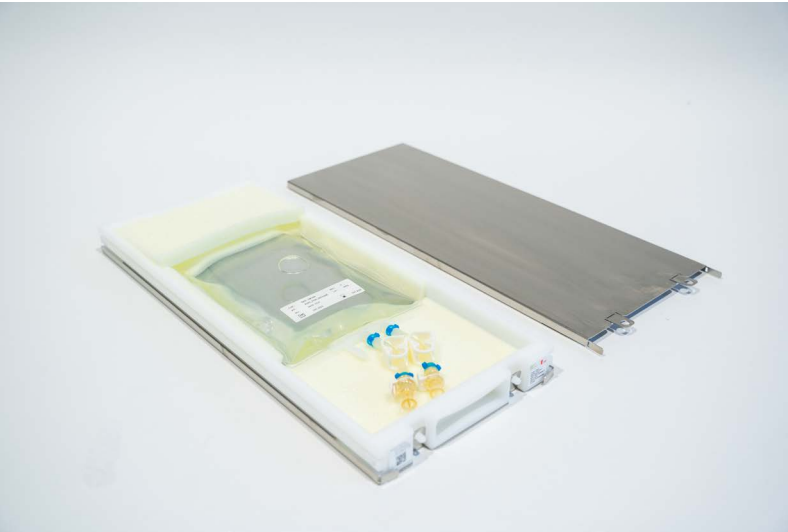
\*Copies of the test reports are available upon request.

Validation against ASTM D-1003, ASTM D-882, ASTM D-792, ASTM F-1249, ASTM D-3985, ASTM F-2476, ISO 1133, ISO 868



# RoSS® Shell

## Robust Storage and Shipping



### **100% safe liquid handling & 0% product loss**

Protect your single-use bag with the safest transport solution: **RoSS® Shell**.

It is a robust case designed to protect 2D single-use bags of any size and vendor in any process step. The shell is optimized for transport, freeze and thaw steps, in which manufacturers see product loss of around 1.5% with traditional methods. In over 300,000 RoSS® Shells sold the product loss was <0.001%.

### **Facts**

Suitable for all sizes of 2D single-use bags and from any manufacturer

Robust, closed and tamper-evident construction, consisting of a stainless steel top and bottom lid and a robust plastic frame

Full immobilisation with 3D foam

Optimal freeze-thaw characteristics

Reduced product loss down to <0.001%

Highest storage density



**Single Use Support assists you from beginning to end, offering highly qualified support all along the way. Contact us for further details!**