SEAMLESS BIO
HIGH PERFORMANCE

CUSTOM SINGLE-USE SYSTEMS

Single-Use Bioprocess Bags

2D bags, 3D bags, rocker bags and tank liners — built to your drawing, gamma-sterilised and supplied with the documentation your QA needs.





50 mL – 5,000 L
2D AND 3D VOLUMES

ISO Class 7
CLEANROOM MANUFACTURING

SAL 10^{-6}
GAMMA, ISO 11137

USP Class VI
FLUID-CONTACT FILM

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YOUR BAG, YOUR PROCESS

Standard bags rarely fit. So we build yours.

Most single-use projects start with a compromise: a catalogue bag that is almost right. We take the other route. You tell us volume, ports, tubing and connectors — we turn it into a technical drawing, you approve it, and the assembly is produced, gamma-sterilised and shipped with full documentation. From the first 100 pilot units to serial supply.

OPEN ARCHITECTURE

Any tubing, filter or connector

We integrate components from all major brands. Your validated connectors stay in your process.

ONE FILM

Multilayer PE/EVOH film

A single, fully documented fluid-contact film for all bag types: animal-free, low extractables, USP Class VI.

STERILE

Gamma-sterilised, SAL 10^{-6}

Validated per ISO 11137 / ISO 13004 (VDmax25). Dose validation tailored to your needs on request.

DOCUMENTED

CoA with every lot

Particles (USP <788>), sterility and endotoxin per lot. Validation guide, E&L data and declarations on request.

FAST

Weeks, not months

Typically 2–3 weeks for 100 units and 5–6 weeks per 10,000 units after drawing approval.

LOCAL PARTNER

Contract and support in DACH

Your contact is in Germany or Switzerland. Invoicing in EUR, USD or CHF.

2D · 3D
PILLOW, CUBE, ROCKER, LINER

−80 °C
FREEZE–THAW TESTED

90 days
UNSUPPORTED HOLD, 1,000/2,000 L

BPOG
EXTRACTABLES PROFILE, USP <665>

TYPICAL APPLICATIONS

Media preparation · Buffer storage · Sampling · Fluid transfer · Bulk intermediate storage · Harvest · Seed train / rocking bioreactors · Freezing & cold storage · Human serum & plasma filling · Diagnostics & R&D

01

BAG STYLES & VOLUMES

Four formats, one film

Choose the format by volume and handling. All formats use the same fluid-contact film and the same documentation package.



50 mL – 50 L

2D bags (pillow)

Two film panels sealed on all sides. Hung from the eyelets or laid flat — no support container needed. Ports sealed into the seam.

- Media and buffer preparation, storage, transport
- Sampling and small-volume transfer

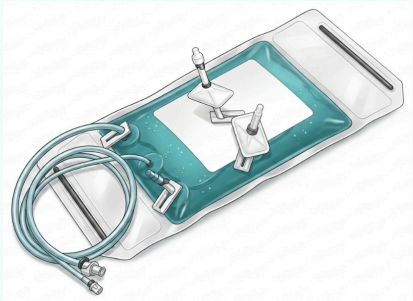


50 L – 5,000 L

3D bags (cube)

Several film panels form a cuboid that fills its support container. Ports welded into the faces, e.g. bottom drain and top fill.

- Bulk media, buffer and intermediate storage
- 1,000 L and 2,000 L bags held 90 days unsupported without leakage

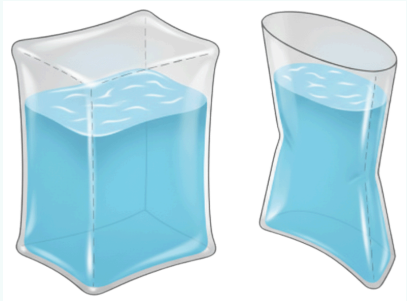


Matched to your rocker

Rocker & wave bags

Flat cell-culture bags for rocking-motion bioreactors, with inlet, outlet, sampling and gas lines configured to your platform.

- Seed trains and suspension culture
- Viral vector and cell therapy upstream



Made to your tank

Tank liners

Open-top liners that turn your existing stainless-steel or plastic tank into a single-use system — no CIP/SIP, no cleaning validation.

- Media preparation with top-down mixers
- Multi-product facilities

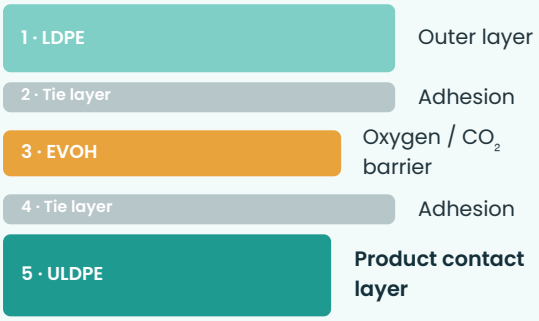
Need support hardware? Stainless-steel containers for 3D bags (200 / 500 / 1,000 L) are configured and assembled in Germany to fit your bag.

FLUID-CONTACT FILM

02 Five layers. One inert contact surface.

All bags are made from a 0.325 mm multilayer film manufactured in the EU. The product only touches an inert ULDPE layer; an EVOH core blocks oxygen and CO_2. The film contains no animal-derived components and no phthalates, plasticisers or fillers.

FILM STRUCTURE (OUTSIDE → PRODUCT)



Heat-sealed · Gamma ≤ 50 kGy · E-beam · X-ray · Animal-free · Low E&L

Property (MD/TD)	Typical value	Method
Thickness	0.325 mm	—
Haze / clarity	7 % / 97 %	ASTM D1003
Light transmittance	93 %	ASTM D1003
Tensile strength at break	14 / 13 MPa	ASTM D882
Elongation at break	370 / 350 %	ASTM D882
Elastic modulus	250 / 270 MPa	ASTM D882
Cold break	below -45 °C	ISO 8570
Density	0.9 g/cm³	ASTM D792
WVTR (23 °C, 100 % RH)	0.35 / 0.32 g/m²/day	ASTM F1249
O_2 transmission (23 °C, 0 % RH)	< 0.05 cm³/m²/day/bar	ASTM D3985
CO_2 transmission (23 °C, 0 % RH)	< 0.2 cm³/m²/day/bar	ASTM F2476

PHARMACOPOEIA & BIOCOMPATIBILITY OF THE FILM

- USP <88> Class VI · USP <87> cytotoxicity
- USP <85> bacterial endotoxins (LAL)
- USP <661.1> plastic materials of construction
- Ph. Eur. 3.1.5 (polyethylene with additives)
- ISO 10993-4 haemolysis · -5 cytotoxicity
- ISO 10993-6 implantation · -10 irritation & sensitisation
- ISO 10993-11 acute systemic toxicity
- EU 10/2011 and 21 CFR 177.1520 food contact

03

CONFIGURE YOUR ASSEMBLY

Every element is your choice

Chamber, ports, tubing and end connections are defined together with you and fixed in an approved technical drawing. Example from a current project: **1 L 2D bag assembly, 3 ports, 3 × ¼″ hose barb**.

01

Chamber

2D, 3D, rocker or liner. Volume, dimensions, eyelets and hanging options to your equipment.

02

Ports

Seam ports for 2D bags, **face (flange) ports** for 3D bags. Number, size and position as needed — e.g. top fill, bottom drain, sampling.

03

Tubing

Silicone, weldable TPE or other materials. Length and inner diameter to your line. Brand-independent.

04

Connections

Hose barbs, Luer lock, tri-clamp and aseptic connectors (e.g. MPX/MPC), gendered or genderless.

05

Filters & accessories

Vent and liquid filters, pinch clamps, sampling lines, caps and plugs.

06

Packaging & label

Double-bagged in cleanroom-grade LDPE, labelled with part number, lot, quantity, expiry and sterility indicator.

YOUR CONFIGURATION CHECKLIST — SEND US THESE POINTS AND WE PREPARE THE DRAWING

- Bag style and working volume
- Application and fluid (pH, solvents, surfactants)
- Process temperature, freezing required?
- Number, type and position of ports
- Tubing material, inner diameter and lengths
- End connectors per line (brand / type)
- Filters, clamps, sampling options
- Sterile or non-sterile, required dose
- Support container / rocker platform model
- Quantity per year and per delivery

Already using a bag from another supplier? Send us its drawing or a photo with dimensions — we build a matching assembly with your existing connectors.

04

QUALITY, STERILITY & COMPLIANCE

Made clean. Proven sterile.

MANUFACTURING

- ISO Class 7 cleanroom
- ISO 9001 and ISO 13485 quality system
- Full lot traceability
- Dimensions and BOM checked per order
- Shelf life by accelerated ageing (ASTM F1980)

STERILISATION

- In-house gamma irradiation
- Validated per ISO 11137 / ISO 13004
- SAL 10^{-6}, VDmax25 or tailored dose
- Typical dose 25–40 kGy
- Film qualified up to 50 kGy

PER-LOT RELEASE (COA)

- Particles per USP <788>
- Sterility assurance per ISO 11137
- Endotoxin ≤ 0.01 EU/mL (LAL, kinetic chromogenic)
- Bioburden per ISO 11737

Area	Standard / regulation	Status
Biological reactivity	USP <87> in vitro · USP <88> Class VI · ISO 10993-4/-5/-6/-10/-11	**Compliant**
Extractables	USP <665>, BPOG standardised protocol	**Profile available**
Plastic materials	USP <661.1> · Ph. Eur. 3.1.5 · Ph. Eur. 5.20 / USP <232>/<233>	**Compliant**
Particulate matter	USP <788> (≥ 10 µm, ≥ 25 µm)	**Tested per lot**
Endotoxin / pyrogens	USP <85> · ISO 11737-3 (LAL)	**Tested per lot**
Food contact & migration	EU 10/2011 (EN 1186, OM2) · 21 CFR 177.1520 · BPA-free	**Compliant**
Animal origin	TSE/BSE-free per EC 999/2001 and EMA/410/01 rev. 3	**Free**
Substances of concern	REACH · RoHS · no PFAS, latex, nitrosamines, SVHC, GMO, residual solvents (ICH Q3C)	**Free**
Nucleases	DNase / RNase	**Free**

Material and compliance statements are based on supplier certifications, historical data and periodic representative testing; they are not lot-specific unless stated on the CoA.

05

VALIDATION DATA

Tested before you test

2D and 3D bags were qualified (IQ / OQ / PQ) on representative sizes and production lots. Summary of results — the full validation guide is available for your supplier qualification.

Test	Standard	Result
Leak (bubble emission)	ASTM E515 / F2096	No bubbles under pressure
Connection firmness	Internal method	No dropout at 15 N for 15 s
Heat-seal strength	ASTM F88	> 50 N / 15 mm, no separation
Tensile & elongation	ASTM D882	Meets film specification (see page 04)
Drop test	ASTM D4169	No rupture or leakage
Unsupported hold	Internal method	1,000 L and 2,000 L: no leakage after 90 days
Weight loss	Internal method	No significant change after 30 days, RT
Insoluble particles	USP <788>	≥ 5, ≥ 10, ≥ 25 µm within limits
Pressure decay	ASTM F2095	Pressure drop ≤ 10 %
Seal integrity (dye)	ASTM F1929	No dye penetration
Freeze–thaw	Internal method	Repeated cycles to -80 °C, no leakage or seal failure

EXTRACTABLES STUDY (BPOG)

Bag film extracted with the BPOG model solutions, including 0.5 M NaOH, 0.1 M H_3PO_4, 5 M NaCl and 1 % polysorbate 80, at T0, 24 h, 21 days and 70 days (40 °C).

Analytics: GC-MS/FID, LC-MS, ICP-MS, TOC and pH.

USE IT FOR YOUR RISK ASSESSMENT

The aggregated tables list all organic extractables and metal ions above the reporting threshold — the basis for your leachables assessment per USP <1663>/<1664>.

Full report on request, under NDA if required.

06

DOCUMENTATION & ORDERING

From drawing to delivery

01
Brief
Send the checklist (page 05), a sketch or an existing drawing.

02
Drawing
We prepare the technical drawing and quote. You approve it.

03
Pilot
Typically 2–3 weeks for 100 units after approval.

04
Supply
About 5–6 weeks per 10,000 units, scheduled to your forecast.

Documentation package

EVERY LOT	**Certificate of Analysis** — particles, sterility, endotoxin, material and BSE/TSE statements
EVERY LOT	**Labelled double packaging** with lot, expiry and sterility indicator
ON REQUEST	**Validation guide** 2D & 3D bags (IQ/OQ/PQ, test results)
ON REQUEST	**Extractables study** summary (BPOG, USP <665>)
ON REQUEST	**Sterilisation validation** and radiation processing certificate
ON REQUEST	**Film technical data sheet**
ON REQUEST	**Declarations:** migration (EU 10/2011), food contact, gamma compatibility, regulatory compliance

GOOD TO KNOW

- Drawings and part numbers are fixed per project — no silent changes
- Serial supply planned to your forecast
- Pilot quantities from 100 units
- Delivery to DE, EU and CH; invoicing in EUR, USD or CHF
- Matching human serum, media and buffers from one supplier — e.g. human serum filled in single-use bags

Send us your bag requirements
Volume, ports, tubing, connectors and quantity are enough to start.
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