

VALBIOPURE SINGLE-USE SYSTEM BAG



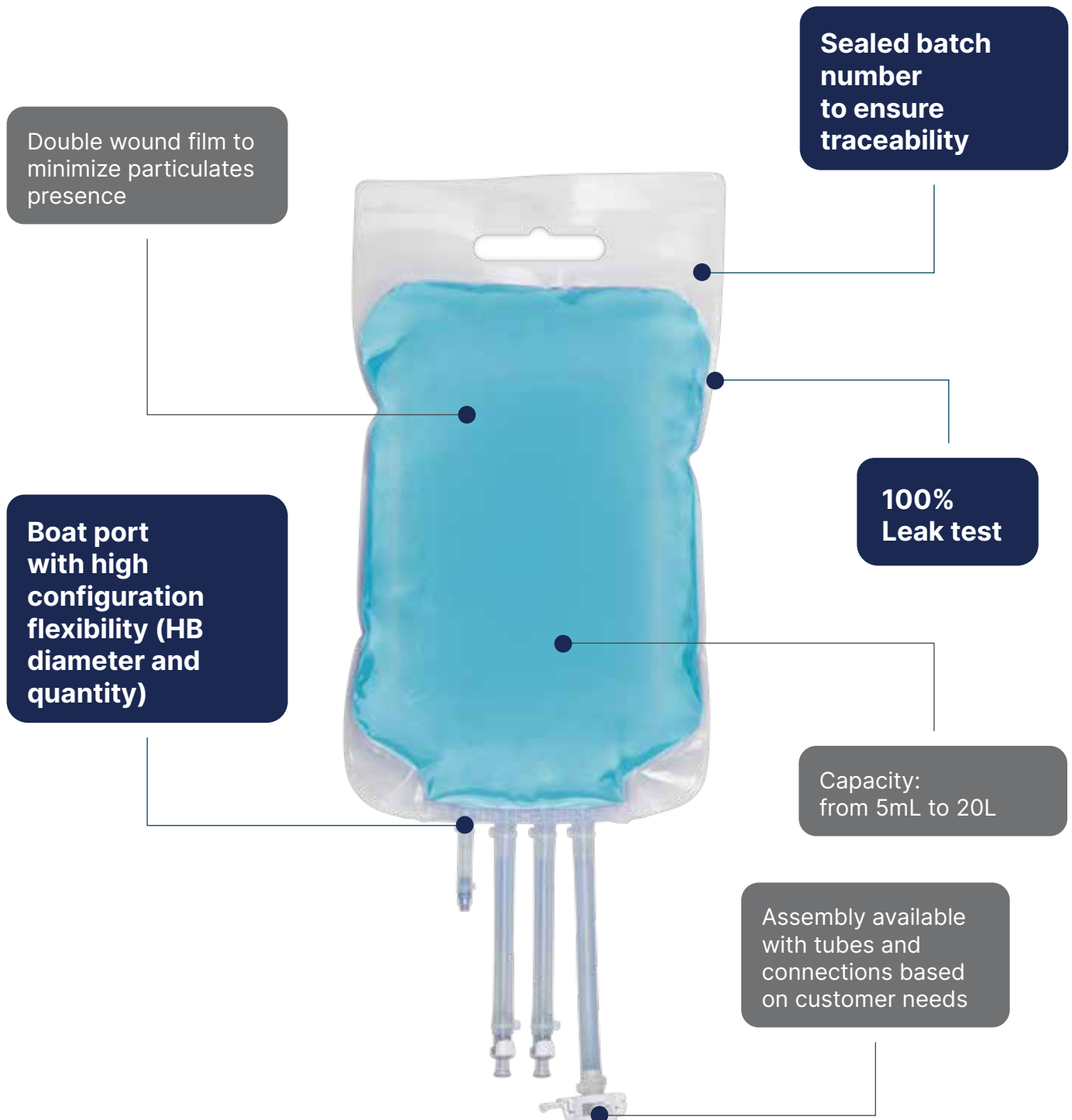
CUSTOMIZED
2D-3D BAG
UP TO 3000L

www.valmedsrl.com



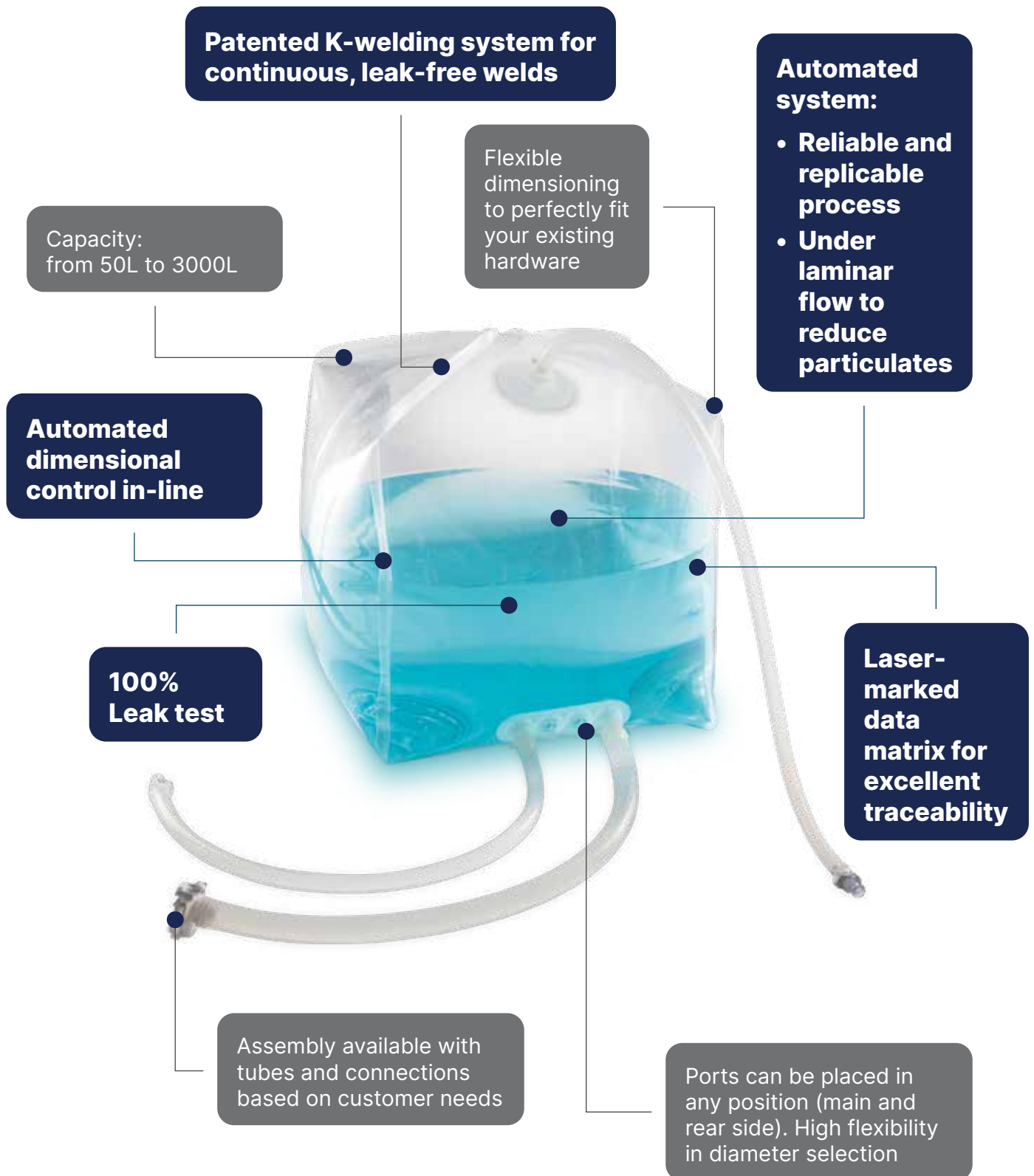
WHY CHOOSE VALBIOPURE?

Discover the unique strengths of our 2D bag



FLEXIBLE, RELIABLE, CUSTOMIZABLE

Discover the unique strengths of our innovative 3D bag



WHAT MAKES VALBIOPURE DIFFERENT?

**Long experience in the medical devices market.
Production of 20Mln bags/year and >100 workers**

**Excellent
customized
MOQ**

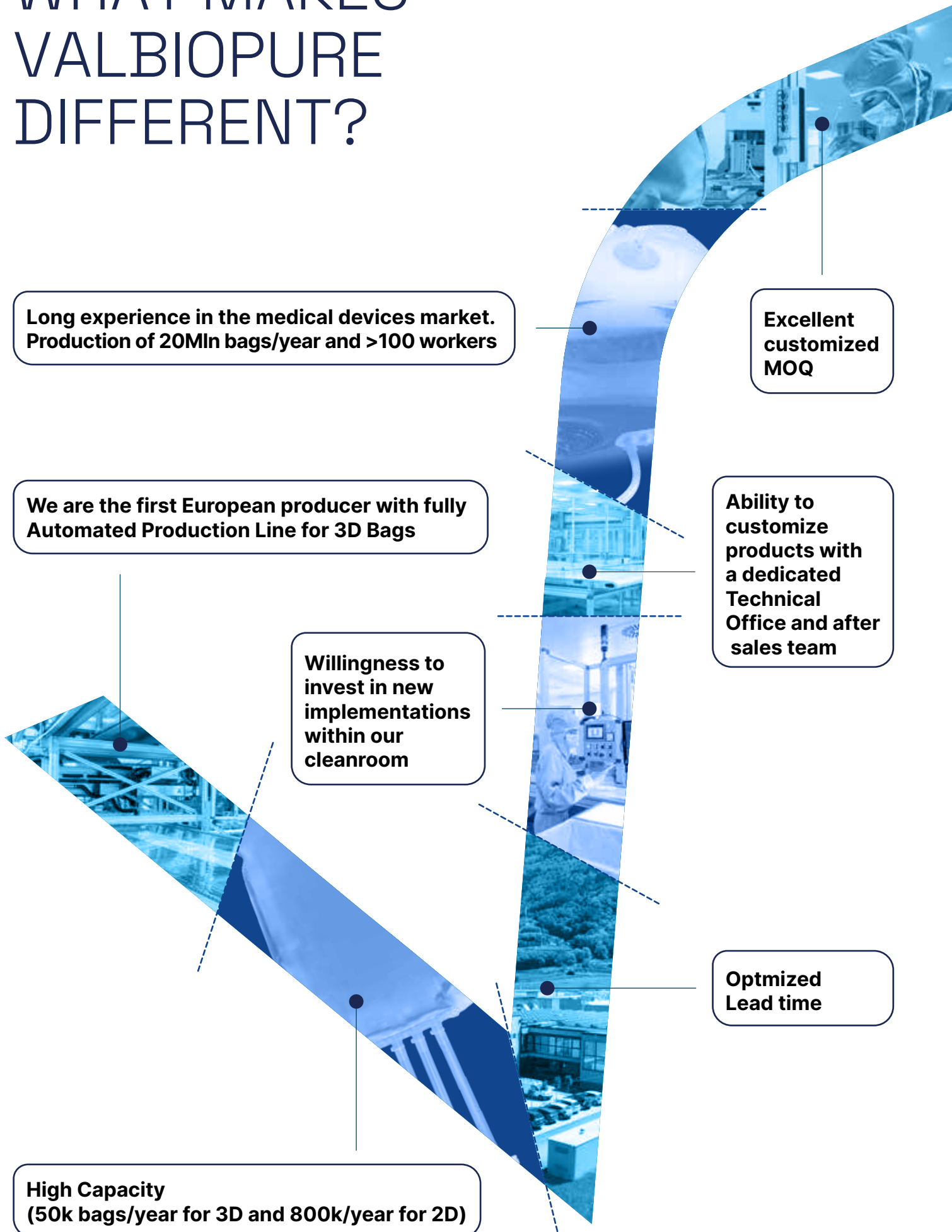
**We are the first European producer with fully
Automated Production Line for 3D Bags**

**Ability to
customize
products with
a dedicated
Technical
Office and after
sales team**

**Willingness to
invest in new
implementations
within our
cleanroom**

**Optimized
Lead time**

**High Capacity
(50k bags/year for 3D and 800k/year for 2D)**



VALIDATION AND QUALITY ASSURANCE

Quality specifications

- Manufactured in ISO 7 cleanroom ISO 14644
- Quality system in according to ISO 13485
- Suitable for Gamma irradiation
- 100% 2D bags leak test.
Coming soon: 3D bags leak test
- The materials which compose the ValBioPure bags comply with:
 1. Biocompatibility requirements (USP class VI and ISO10993)
 2. REACH regulation and free from animal derivatives
 3. Physico-chemical test requirements for pharmaceutical containers (Ph. Eur. 3.1 / USP <661.1>-<661.2>)

Qualification studies

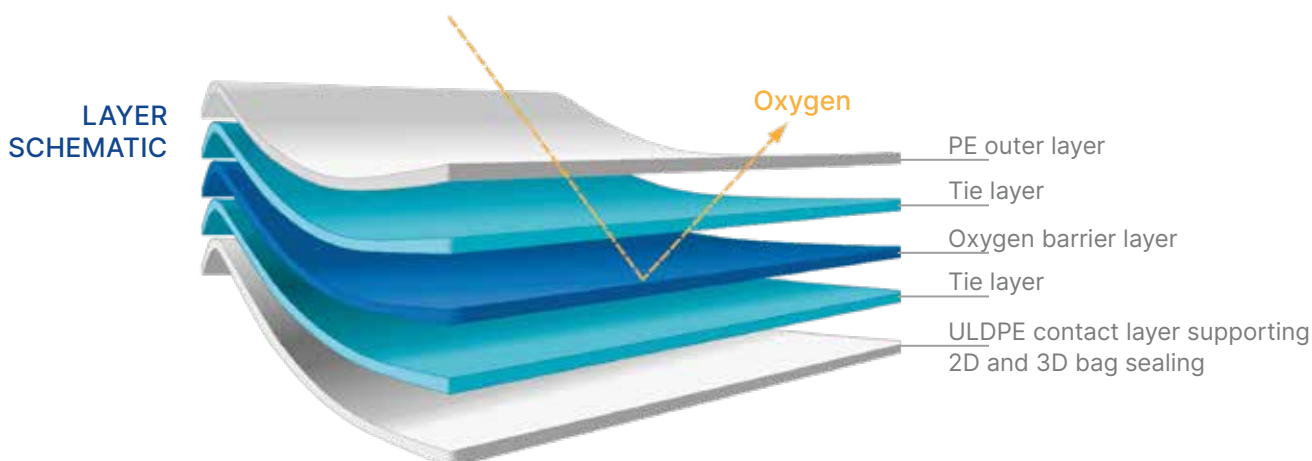
- Extractable Study (USP <1665>, USP <665> / BPOG Guidance)
- Physico-chemical material properties and Chemical compatibility chart
- Validation tests including:
 1. Mechanical Tests including drop test, leak test, connection test, tensile test and hanging test
 2. Gamma Sterilization, Filling and Transport Resistance
 3. Resistance to Freezing Test up to -80°C
 4. Physico-chemical Testing (USP <661.2>, Ph. Eur. 2.6.14, USP <788> and USP <790>)
 5. 3 year Shelf-Life (accelerated testing 40°C, 75% RH and real-time testing 25°C, 60% RH).

RENOLIT GRANUFLEX 4301 PE port specifications

- Valmed brand-owned mold design
- High-precision injection molding technique
- The selected PE granule demonstrates lower leachable levels and high purity
- Strong uniformity and compatibility with film
- Customizable configuration including port arrangement, number and diameters

RENOLIT INFUFLEX 9101: PE film specifications

- Made with five-layer coextruded film with a total thickness of 0.325mm and PE fluid contact layer
- The barrier film is made of ultra-pure inert PE inner and outer layers
- The high barrier properties combined with the oxygen barrier layer (EVOH) offer significant advantages in oxygen-sensitive products storage
- The selected film demonstrates ultra-low extractables and leachables level and excellent clarity



THE REVOLUTIONARY PATENTED K WELDING



The advantages of our seamless K-Weld technology give rise to three distinctive K-Families: **Kube** delivers a perfectly cubic geometry, **Kolumn** offers a tall and narrow profile, and **Kontainer** provides a wide, low-height configuration.

Beyond these families, our system ensures full production flexibility, allowing the creation of customized dimensions tailored to your specific requirements.

Kube



Kolumn



Kontainer

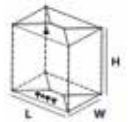


BAG MODELS



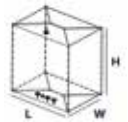
Kolumn 3D bag

Capacity (L)	L (mm)	W (mm)	H (mm)
50	345	320	720
100	425	400	755
200	510	485	940
300	545	520	1250
370	630	605	1150
560	695	670	1425
750	790	765	1330
1000	915	890	1270
1300	1045	1020	1270



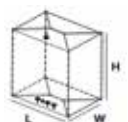
Kontainer 3D bag

Capacity (L)	L (mm)	W (mm)	H (mm)
100	745	545	285
200	760	570	525
500	1130	740	660
1000	1130	940	1075
1500	1130	940	1670
2000	1130	940	2170
3000	1130	940	3030



Kube 3D bag

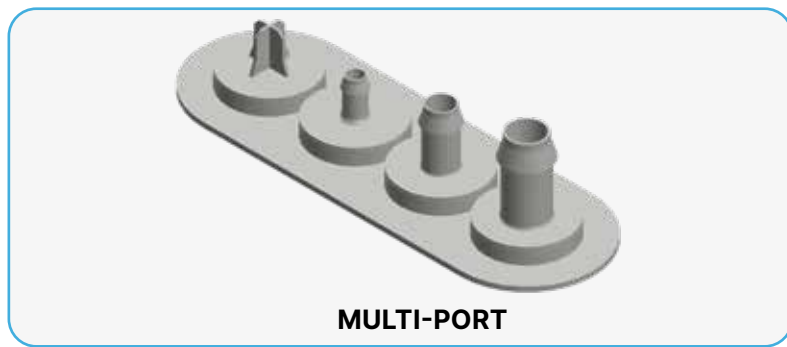
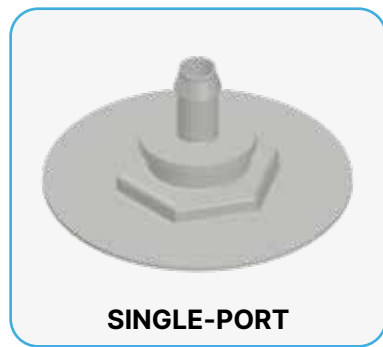
Capacity (L)	L (mm)	W (mm)	H (mm)
50	425	400	425
100	510	485	510
200	630	605	630
400	790	765	790
650	915	890	915
1000	1025	1000	1020



Dimensions shown are for reference only.
Exact dimensions and tolerances are provided in the technical drawing upon request.

3D PORTS

Valmed offers two main port models which can be positioned along the entire surface of the film (main and rear face)



For these models, the diameter can be selected according to the tables below:

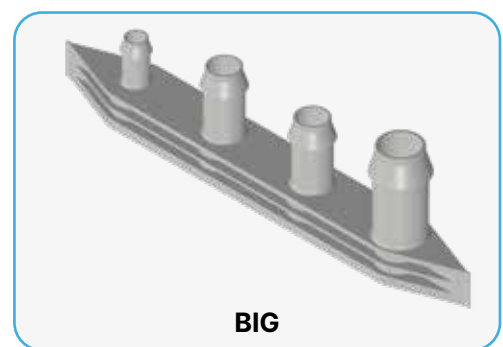
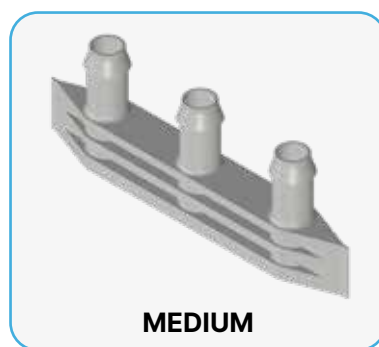
Port model	Port 1 diameter	Port 2 diameter	Port 3 diameter	Port 4 diameter
Single-port	1/4" - 3/8" - 1/2" - 3/4"	N/A	N/A	N/A
Multi-port	1/4" - 3/8" - 1/2" - 3/4" - Closed	1/4" - 3/8" - 1/2" - 3/4" - Closed	1/4" - 3/8" - 1/2" - 3/4" - Closed	1/4" - 3/8" - 1/2" - 3/4" - Closed

In addition to these ports Valmed can seal on the bag chamber:

- Mixer
- Sanitary port
- Single-use sensors
- Multi-use sensor connectors

2D BOAT PORT

Depending on the bag capacity, Valmed offers 3 boat port models



For these models, the diameter can be selected according to the tables below:

Boat port model	Port 1 diameter	Port 2 diameter	Port 3 diameter	Port 4 diameter
Baby	1/8" - 1/4"	N/A	N/A	N/A
Medium	1/8" - 1/4" - None	1/8" - 1/4" - None	1/8" - 1/4" - None	N/A
Big	1/8" - 1/4" - 3/8" - 1/2" - None	1/8" - 1/4" - 3/8" - 1/2" - None	1/8" - 1/4" - 3/8" - 1/2" - None	1/8" - 1/4" - 3/8" - 1/2" - None

BAG MODELS



Baby
5 mL



Medium
From 50 to 1000 mL



Big
From 2 to 20 L



Capacity	H (mm)	L (mm)	Boat port model
5 mL	100	60	Baby
50 mL	150	100	Medium
100 mL	180	100	Medium
250 mL	230	135	Medium
500 mL	270	150	Medium
1 L	330	180	Medium
2 L	380	240	Big
3 L	455	280	Big
5 L	525	300	Big
10 L	630	400	Big
20 L	740	500	Big

BEYOND STANDARD: CUSTOM DESIGNS AVAILABLE

Our engineering process enables complete tailoring of bag geometry, assembly configuration, materials selection, and component integration to meet specific process requirements. Each solution is designed through a controlled process that integrates material expertise, precision tooling, and validated manufacturing methods.

TECHNICAL STRENGTHS

- **Extended Expertise in Custom Medical Devices**

Our background in engineered medical components provides a robust foundation for developing customized SUS designs with attention to quality and physical performance.

- **Dedicated In House Tooling**

Tooling for tailor-made bag shapes, is fully developed internally. This ensures precision, reproducibility, and short lead times during design iteration.

- **Flexible Manufacturing Assets**

The integration of automated equipment with configurable manual workstations provides high adaptability for prototypes, small runs, and preseries production.



Pillow 2D bag

Capacity	Up to 200 L
Film	Infuflex® 9101
Ports	Granuflex® 4301; single-port or multi-port configuration
Sensors	Sensor integration available
Fixation	Rigid tubing for secure fixing
Tubing assembly	Customizable tubing assemblies
Filtration	Compatible with inline / dedicated filters

BAG ASSEMBLIES

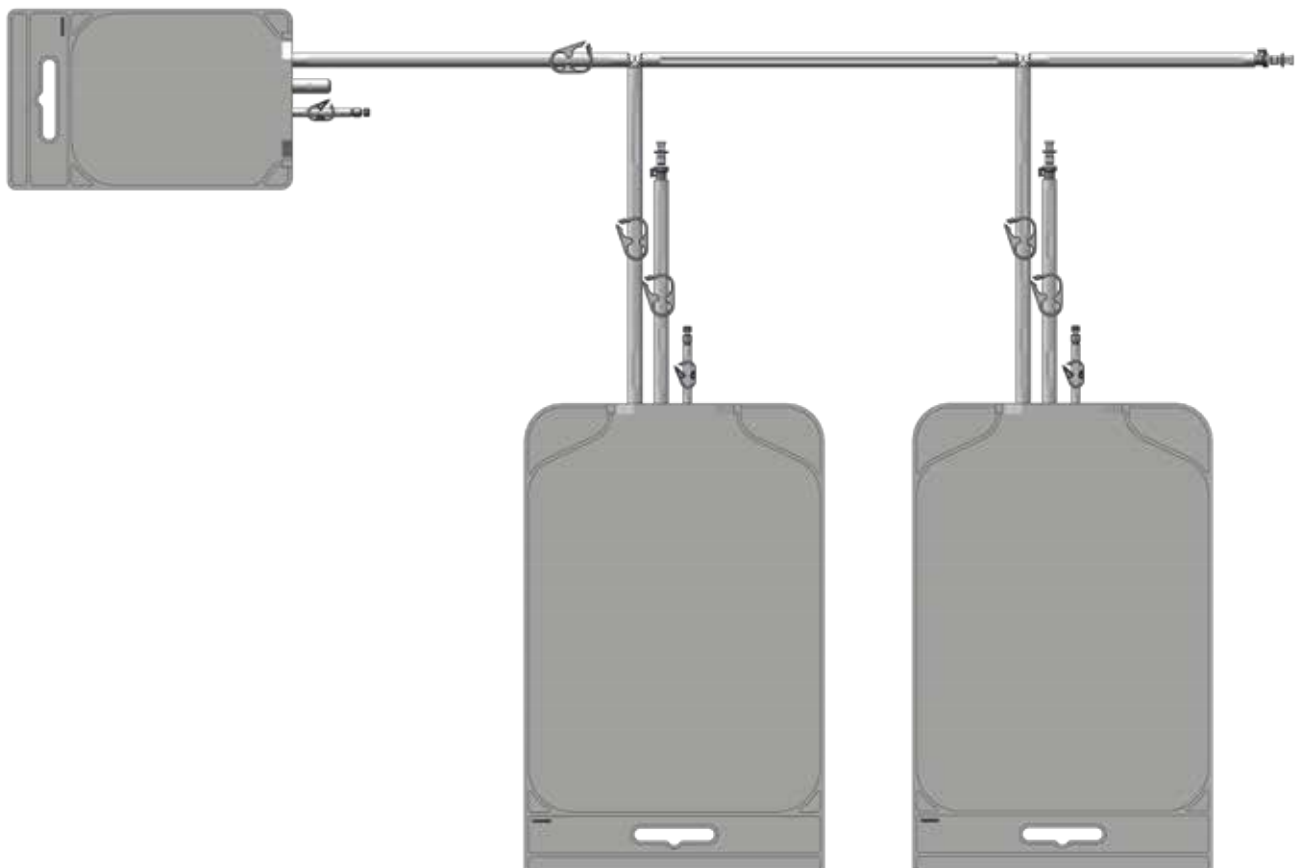
The bag chamber can be completed with tubing and end components according to the customer's specifications.

Valmed performs the entire assembly process in-house within its ISO 7 cleanroom, without involving external subcontractors. This minimizes handling, reduces lead times, and ensures a controlled and streamlined workflow.

Variety of component selection:

- **Tubing:** TPE or silicone
- **Connectors and disconnectors**
- **Fittings**
- **Pinch clamps**
- **Filters**
- **Sensors**
- **Customer specific request**

We offer **fully customized assemblies**, enabling customers to leverage components and configurations they have already validated, or to integrate new tailored solutions.





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