

CLEARLine®
"Be cool, be safe, be CLEARLine"



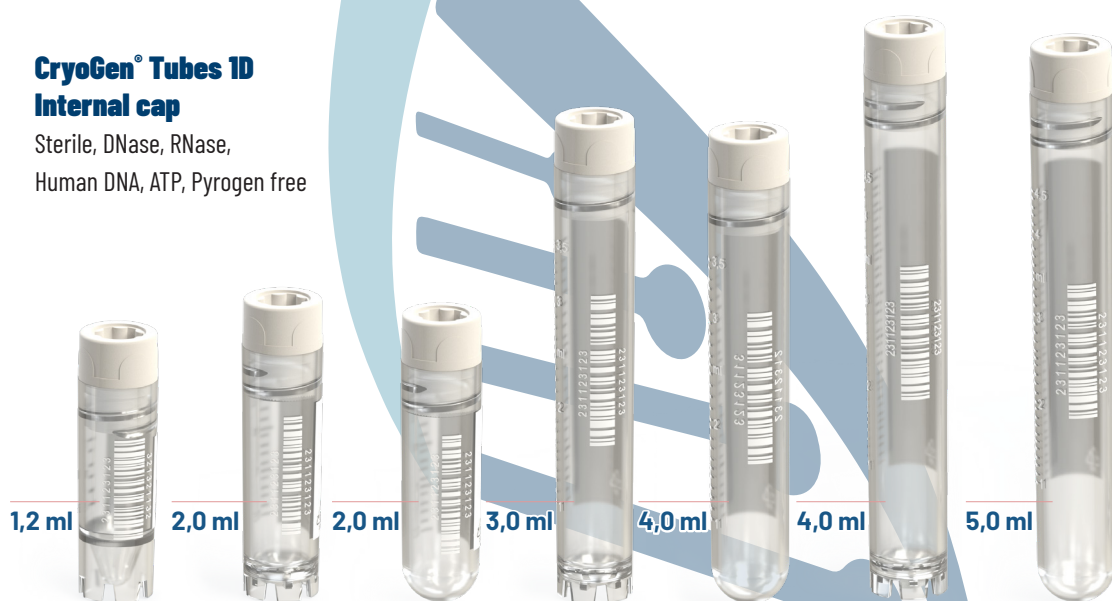
CryoGen® Tubes 1D
External cap

Sterile, DNase, RNase,
Human DNA, ATP, Pyrogen free



CryoGen® Tubes 1D
Internal cap

Sterile, DNase, RNase,
Human DNA, ATP, Pyrogen free



Vial Picker

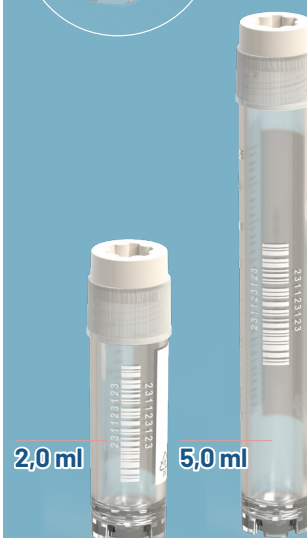
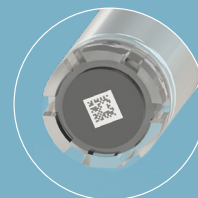


Writing Cap Disks



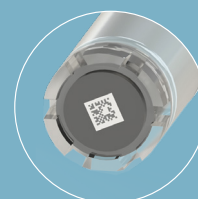
CryoGen Tubes 2D
External cap

Sterile, DNase, RNase,
Human DNA, ATP, Pyrogen free



CryoGen Tubes 2D
Internal cap

Sterile, DNase, RNase,
Human DNA, ATP, Pyrogen free



Biosigma offers a complete range of cryogenic tubes and boxes for the preservation of samples in the gaseous phase of liquid nitrogen.

- Biosigma CryoGen® tubes are manufactured from premium-quality virgin, medical-grade PP/PE, free from biocides, plasticizers and latex
- Produced using optimized, high-gloss polished moulds, without slip additives such as oleamide, erucamide or stearamide
- Certified free from human DNA, DNases, RNases, Endotoxins, PCR inhibitors, Sterile SAL 10-6, IATA PI 650 and do not contain traces of metals
- Each tube features a unique and consecutive barcode in 1D format printed on the tubes' bodies
- The line also includes 2D CryoGen® tubes, with a 2D Data-Matrix code on the bottom of the tubes, in addition to the 1D linear barcode for advanced traceability
- CryoGen® tubes can be stored in Biosigma CryoGen® boxes (25, 81 or 100 places), featuring a 1D linear barcode printed on the side, or in 2D CryoGen® boxes with an additional 2D Data-Matrix code on the bottom for enhanced traceability
- Cryogenic boxes are made of polycarbonate to withstand the temperatures of the gaseous phase in liquid nitrogen. They are autoclavable at 121°C for 20 minutes
- Raw materials are medical-grade and compliant with USP Class VI and ISO 10993 standards, in accordance with the United States Pharmacopoeia



- CryoGen® 1D test tubes with linear barcode
- CryoGen® Box
- CryoGen® 2D barcoded test tubes
- CryoGen® box 2D
- SBS 48-place rack for 2 and 5 ml CryoGen® Tubes
- CryoGen® line accessories



WARNING

Do not dip Cryogen test tubes in the liquid phase of nitrogen. Immersion in the liquid phase may cause liquid nitrogen to become trapped inside the tube, which could lead to an increase in pressure, causing a possible explosion with risk of biological contamination. Make sure samples in the gas phase are stored above the liquid nitrogen. In this state the temperature is below the level required to maintain the material in good condition.

CryoGen® 1D test tubes with linear barcode

CLEARLine®



- Certified batches free from human DNA, DNases, RNases, Endotoxin, ATP and PCR inhibitors*
- Sterile SAL 10⁻⁶ **
- Compliant with IATA regulation PI 650
- Working temperatures: from generic refrigeration (+4°C) up to the gaseous phase of liquid nitrogen
- Medical grade materials
- Test tube body in polypropylene, bi-injected caps in polyethylene and TPE
- Standard code 128 barcode unique and unrepeatable
- No traces of metals found within the detection limits

* Certificate of Analysis downloadable from our website www.biosigma.com
 ** Beta-ray sterilization validated; certificate available for download at www.biosigma.com

Coloured inserts available for colour code adaptable to both internal and external caps for quick identification of the sample

Made of medical grade polyethylene (PE) and elastomer thermoplastic (TPE) to provide a hermetic seal

Test tube body manufactured from medical grade PP

Code 128 barcode on each tube body with double decoding readable in both directions. Each 128 barcode is unique and unrepeatable

Star shaped top cavity is engineered for use with automatic decapping equipment

Excellent chemical resistance of the cap

Thin profile external cap to ensure better insertion into standard racks and storage boxes

Test tubes and caps are autoclavable at 121°C for 20 minutes

Printed graduations

Large writing area

Excellent chemical resistance

With or without base

Test tube with self-locking base in workstations

Our bi-injected screw caps make it possible to eliminate sample leakage and contamination. Both the inner and outer screw caps are co-moulded with PE and a thermoplastic elastomer (TPE) to provide a perfect seal. This bi-injection moulding process eliminates the risk of contamination associated with the insertion of separate o-rings.

For further information, please refer to the technical data sheet downloadable from our website www.biosigma.com

**500-piece dispenser box
(10 50-piece zip-bags)**

50-piece zip-bags with indication of sterilisation

CryoGen® 1D test tubes with linear barcode



CryoGen® test tubes with internal cap

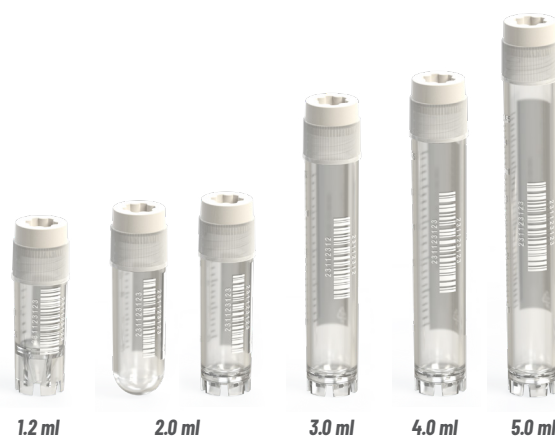
Sterile, free from DNases, RNases, human DNA, ATP, Endotoxins, PCR inhibitors and Metals



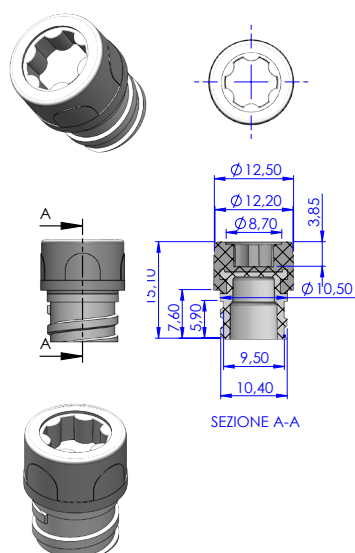
Code	Vol. (ml)	Height (cm)	Bottom	Units/Bags	Sales units
CL1ARBIPSTS	1.2	4.27	With base	50	500
CL2ARBIPSTS	2.0	4.82	With base	50	500
CL2ARIPSTS	2.0	4.70	Without base	50	500
CL4ARBIPSTS	4.0	7.62	With base	50	500
CL4ARIPSTS	4.0	7.50	Without base	50	500
CL5ARBIPSTS	5.0	9.03	With base	50	500
CL5ARIPSTS	5.0	8.92	Without base	50	500

CryoGen® test tubes with external cap

Sterile, free from DNases, RNases, human DNA, ATP, Endotoxins, PCR inhibitors and Metals



Code	Vol. (ml)	Height (cm)	Bottom	Units/Bags	Sales units
CL1ARBEPSTS	1.2	4.02	With base	50	500
CL2ARBEPSTS	2.0	4.56	With base	50	500
CL2AREPSTS	2.0	4.45	Without base	50	500
CL3ARBEPSTS	3.0	6.92	With base	50	500
CL4ARBEPSTS	4.0	7.36	With base	50	500
CL5ARBEPSTS	5.0	8.76	With base	50	500



For automatic capper/decapper

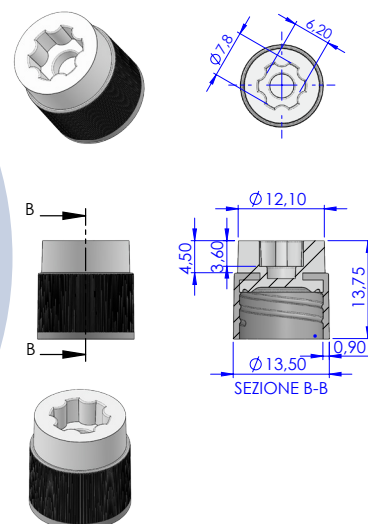
Star shaped top cavity is engineered for use with automatic decapping equipment.

No risk of contamination

Our bi-injected screw caps make it possible to eliminate sample leakage and contamination. Both the inner and outer screw caps are co-moulded with PE and a thermoplastic elastomer (TPE) to provide a perfect seal. This bi-injection moulding process eliminates the risk of contamination associated with the insertion of separate o-rings.

Insert for color coding

Color coded inserts are available to fit both internal and external caps for quick sample identification.



All CLEARLine® cryogenic tubes with standard barcode on this page are available with coloured caps.

Add the following suffixes to the references when ordering:



Colour	Light Blue	White	Yellow	Red	Purple	Green
Suffix	/AZ	/BI	/G	/R	/VI	/V
For example	CL1ARBEPSTS/AZ	CL1ARBEPSTS/BI	CL1ARBEPSTS/G	CL1ARBEPSTS/R	CL1ARBEPSTS/VI	CL1ARBEPSTS/V

CryoGen® Box

Features

- Suitable for storing CryoGen® 1D test tubes
- Grids available in 4 colours
- Lid positioning, guided by 45° inclined corners
- Frosted writing area on the lid and base, for easy writing
- Working temperatures: from general refrigeration (+4°C) to the gaseous phase of liquid nitrogen
- Autoclavable at +121°C for 20 minutes

Rack 1D additional features

- Laser-engraved barcode "code 128" on the side of the box
- Numeric grid on the lid and bottom

Printed numerical grid
on the lid



Frosted writing
area



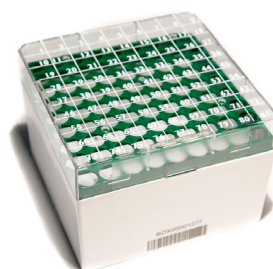
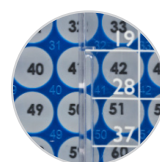
Vial picker included
in each sales unit



1D barcode lasered
on rack's side



Numerical grid on the
bottom and on the lid



CryoGen® Box 81 LOW standard and 1D barcoded for 1 - 2 ml tubes, external and internal cap

Code	1D	Colour	Dimensions (mm)	Sales units
BSM58061B/AZ		Light Blue	132 x 132 x 52	40
BSM58061B/RO		Red		40
BSM58061B/V		Green		40
BSM58061B/G		Yellow		40
BSM58061B1D/AZ	X	Light Blue		40
BSM58061B1D/G	X	Yellow		40
BSM58061B1D/RO	X	Red		40
BSM58061B1D/V	X	Green		40

CryoGen® Box 81 HIGH standard and 1D barcoded for 3 - 4 - 5 ml tubes external cap and 5 ml internal cap

Code	1D	Grid colour	Dimensions (mm)	Sales units
BSM58071B/AZ		Light Blue	132 x 132 x 94	32
BSM58071B/G		Yellow		32
BSM58071B/RO		Red		32
BSM58071B/V		Green		32
BSM58071B1D/AZ	X	Light Blue		32
BSM58071B1D/G	X	Yellow		32
BSM58071B1D/RO	X	Red		32
BSM58071B1D/V	X	Green		32



CryoGen® Box 25 standard and 1D barcoded for 1 - 2 ml tubes, external and internal cap

Code	1D	Colour	Dimensions (mm)	Sales units
BSM58025B/AZ		Light Blue	76 x 76 x 52	48
BSM58025B/RO		Red		48
BSM58025B/V		Green		48
BSM58025B/G		Yellow		48
BSM58025B1D/AZ	X	Light Blue		48
BSM58025B1D/RO	X	Red		48
BSM58025B1D/V	X	Green		48
BSM58025B1D/G	X	Yellow		48

CryoGen® Box 100 standard 1D barcoded for 1 - 2 ml tubes, internal cap

Code	1D	Colour	Dimensions (mm)	Sales units
BSM58100/AZ		Light Blue	132 x 132 x 52	40
BSM58100/B		White		40
BSM58100/G		Yellow		40
BSM58100/RO		Red		40
BSM58100/V		Green		40
BSM581001D/B	X	White	132 x 132 x 52	40

CryoGen® 2D barcoded test tubes



Coloured inserts available for colour code adaptable to both internal and external caps for quick identification of the sample

Star shaped top cavity is engineered for use with automatic decapping equipment

Excellent chemical resistance of the cap

Thin profile external cap to ensure better insertion into standard racks and storage boxes

Excellent chemical resistance of the test tube

Code 128 barcode on each test tube with double decoding readable in both directions and corresponding to the 2D code on the bottom. Each 128 barcode is unique and unrepeatable

The base of the tube is provided with channels to expel cryogenic liquid that could be trapped between the base of the tube and the 2D pad.

Test tube with self-locking base in workstations.

Bi-injected internal and external screw caps manufactured from medical grade polyethylene (PE) and thermoplastic elastomer (TPE) to provide a hermetic seal

Printed graduations

Large writing area

Test tube body manufactured from medical grade PP

Datamatrix code inserted in the bottom, sequential and corresponding to the "code 128" barcode on the test tube body.

Permanent laser marking system, subjected to rigorous quality controls.

The insert bearing the 2D code is fixed in position by using ultrasound (patented system).

- Certified batches free from human DNA, DNases, RNases, Endotoxin, ATP and PCR inhibitors*
- Sterile SAL 10⁻⁶ **
- Compliant with IATA regulation PI 650
- Working temperatures: from generic refrigeration (+4°C) to the gaseous phase of liquid nitrogen

- No traces of metals found within the detection limits
- Made of medical grade materials
- Test tube body in polypropylene, bi-injected caps in polyethylene and TPE
- Autoclavable at +121°C for 20 minutes

* Certificate of Analysis downloadable from our website www.biosigma.com
** Validated beta-ray treatment certificate, downloadable from our website

For further information, please refer to the technical data sheet downloadable from our website www.biosigma.com

CryoGen® 2D test tubes with internal cap

Sterile, free from DNases, RNases, human DNA, ATP, Endotoxins and PCR inhibitors



Code	Vol. (ml)	Height (cm)	Units/Bags	Sales units
CL2ARBIPS2D	2.0	4.82	50	500
CL5ARBIPS2D	5.0	9.03	50	500

CryoGen® 2D test tubes with external cap

Sterile, free from DNases, RNases, human DNA, ATP, Endotoxins and PCR inhibitors



Code	Vol. (ml)	Height (cm)	Units/Bags	Sales units
CL2ARBEPS2D	2.0	4.56	50	500
CL5ARBEPS2D	5.0	8.76	50	500

CryoGen® box 2D

- Laser-engraved barcode "Code 128" on the side of the box
- Datamatrix 2D Barcode on the bottom of the box, for rack recognition and orientation
- Grids available in 4 colours
- In polycarbonate
- Suitable for storing CryoGen® 2D test tubes
- Lid positioning, guided by 45° inclined corners
- Frosted writing area on the lid and base, for easy writing
- Resistant up to the gaseous phase of liquid nitrogen
- Autoclavable at +121°C for 20 minutes

Automatic rack orientation



One-handed opening



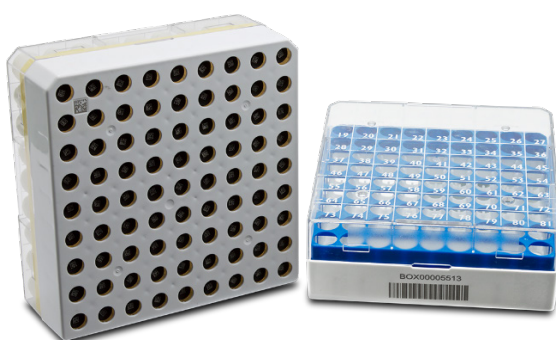
Numbered grid and lid



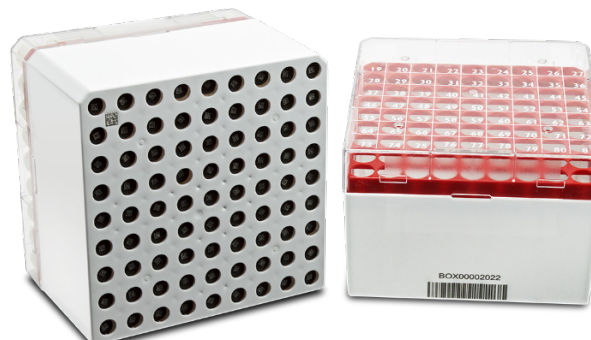
Frosted writing area



Barcode on the side of the rack



81-place 2D box, low bottom



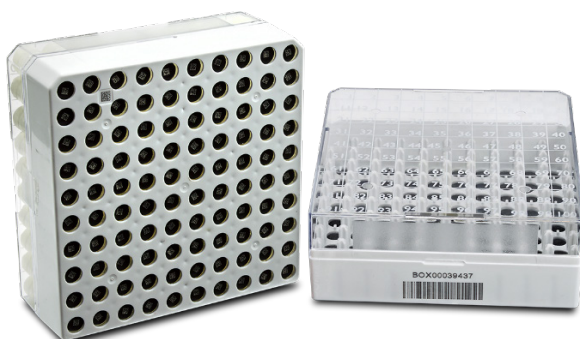
81-place 2D box, high bottom

Box 81 LOW pad printed grid lid 2D for 2 ml tubes

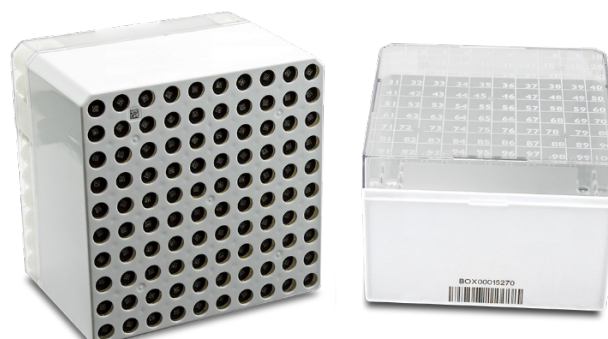
Code	Places	Colour	Dimensions (mm)	Sales units
BSM580612D/AZ	81	Light Blue	132 x 132 x 52	40
BSM580612D/RO	81	Red		
BSM580612D/V	81	Green		
BSM580612D/G	81	Yellow		

Box 81 HIGH pad printed grid lid 2D for 5 ml tubes

Code	Places	Colour	Dimensions (mm)	Sales units
BSM580712D/AZ	81	Light Blue	132 x 132 x 94	32
BSM580712D/RO	81	Red		
BSM580712D/V	81	Green		
BSM580712D/G	81	Yellow		



100-place 2D box, low bottom



100-place 2D box, high bottom

Box 100 LOW pad printed grid lid 2D for 2 ml tubes, internal cap

Code	Places	Colour	Dimensions (mm)	Sales units
BSM581002D/B*	100	White	132 x 132 x 52	40

*Only compatible with test tubes with internal cap

Box 100 HIGH pad printed grid lid 2D for 5 ml tubes, internal cap

Code	Places	Colour	Dimensions (mm)	Sales units
BSM581052D/B*	100	White	132 x 132 x 94	32

*Only compatible with test tubes with internal cap

SBS 48-place rack for 2 and 5 ml CryoGen® Tubes

CLEARLine®

48-place storage rack in ANSI standard format.

- Bottom with windows for Datamatrix scanning applied to the bottom of the test tube
- Linear barcode on the side of the rack
- Datamatrix on the bottom of the rack for correct orientation on the reading scanner
- Easy one-hand opening thanks to the side flaps
- Can be used on automatic decappers
- Can be used on reading scanners
- In polycarbonate
- Stackable



Reading windows in the bottom



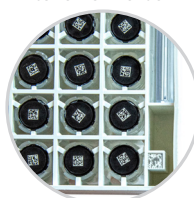
Linear barcode



Easy one-hand opening



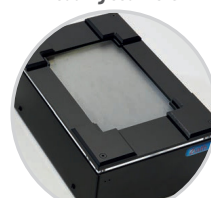
Datamatrix on the bottom of the rack



One-hand screw/unscrew test tubes



Compatible with automatic reading scanners



The CryoGen® tubes 2D contained in the rack are:

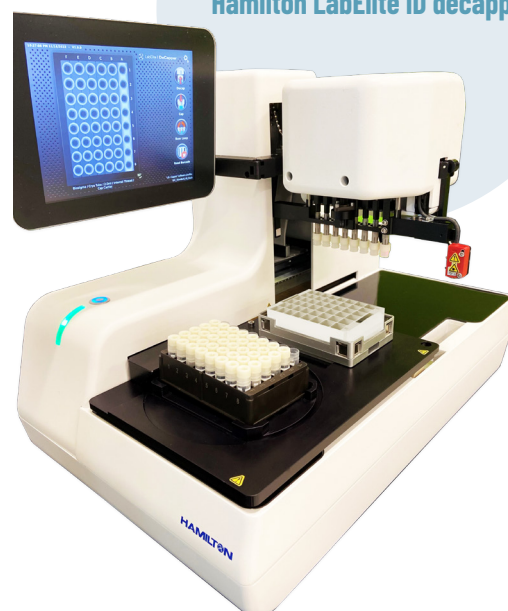
- Certified batches free from human DNA, DNases, RNases, Endotoxin, ATP and PCR inhibitors*
- Sterile SAL 10⁻⁶ **
- Compliant with IATA regulation PI 650
- Working temperatures: from generic refrigeration (+4°C) to the gaseous phase of liquid nitrogen
- No traces of metals found within the detection limits
- Made of medical grade materials
- Test tube body in polypropylene, bi-injected caps in polyethylene and TPE
- Autoclavable at +121°C for 20 minutes

* Certificate of Analysis downloadable from our website www.biosigma.com

** Validated beta-ray treatment certificate, downloadable from our website

For further information, please refer to the technical data sheet downloadable from our website www.biosigma.com

* The rack filled with 2 ml CryoGen 2D tubes, is compatible with the Hamilton LabElite ID decapper



48-place SBS rack with CryoGen® 2D test tubes

Code	Description	Sales units
BSM58048HI	48-place rack with 5 ml CryoGen® 2D test tubes with base - internal cap	10
BSM58048HE	48-place rack with 5 ml CryoGen® 2D test tubes with base - external cap	10
BSM58048LI *	48-place rack with 2 ml CryoGen® 2D test tubes with base - internal cap	20
BSM58048LE *	48-place rack with 2 ml CryoGen® 2D test tubes with base - external cap	20

Empty 48-place SBS racks

Code	Description	Sales units
BSM58048H	48-place rack for 5 ml CryoGen® Tubes 2D	10
BSM58048L	48-place rack for 2 ml CryoGen® Tubes 2D	20

CryoGen® line accessories

Coated cardboard rack

- Dimensions: 133 x 133 mm
- With writing area on the lid
- For freezing down to -196°C



Code	Colour	Height (mm)	Grid	Sales units
010185	White	75	81	1
010186	White	75	100	1
010179	Assorted	50	81	5
010181	Assorted	50	100	5

Workstation for 40 CryoGen® test tubes

CryoGen® test tube Workstation, 40 holes, polycarbonate.

To screw/unscrew test tubes directly on the bench with one hand.

- Available in 3 colours
- In polycarbonate
- Autoclavable
- Housing for 40 test tubes



Code	Colour	Dimensions (mm)	Sales units
BSM5810/AZ	Blue	L 21.5 D 10.0 H 2.50	5
BSM5810/RO	Red	L 21.5 D 10.0 H 2.50	5
BSM5810/V	Green	L 21.5 D 10.0 H 2.50	5

Vial Picker

- Useful for recovering frozen CryoGen® test tubes
- Allows you to screw/unscrew the CryoGen® test tubes with 1 hand



Code	Colour	Sales units
CRY920TS/B	Blue	600

Cryogenic tube and goblet holder

- Aluminium shaft that can hold 3 - 6 cryogenic tubes depending on their height. Length: 28 cm



Code	Description	Sales units
055030	Nunc storage rod Aluminium	50

CLEARLine® white cryogenic box in cardboard

- In hydrophobic cardboard
- Supplied with separators
- Dimensions (mm): 133 x 133 x 50
- 100-place boxes compatible with 0.5/1/2 ml microtubes
- 81-place boxes compatible with CLEARLine® 1/2 ml cryogenic tubes
- Storage temperature: from -196°C to +121°C
- Writable



Code	Grid	Sales units
972015	81	1
972016	100	1

Writable Cap-Disks

- Available in 6 colours
- Can be used with CryoGen® test tube caps



Code	Colour	Sales units
CRY910TS/BI	White	1000
CRY910TS/AZ	Blue	1000
CRY910TS/G	Yellow	1000
CRY910TS/RO	Red	1000
CRY910TS/V	Green	1000
CRY910TS/VI	Purple	1000

Cryomarkers

- 4 colours available
- Ideal for writing on cryogenic tubes, cryogenic boxes and cryogenic supports
- Blue, red and black with extra fine tip
- Green with standard tip



Code	Description	Sales units
028123	Pack of 4 cryomarkers, assorted colours (green, blue, red, black)	4
028124	Pack of 4 black cryomarkers	4

Cryogenic Gloves

Features of standard model:

- Applications: Ultra-cold
- Ultra-low temperature freezers
- Cold room
- Dry ice handling



	SMALL (S)	MEDIUM (M)	LARGE (L)	EXTRA LARGE (XL)	Sales units
5 fingers 30 cm	035501	035502	035503	035504	1
5 fingers 38 cm	035505	035506	035507	035508	1
5 fingers 50 cm	035509	035510	035511	035512	1
5 fingers 68 cm	035513	035514	035515	035516	1

MEDICAL GRADE RAW MATERIALS

Ensuring the safety and effectiveness of pharmaceutical and medical substances requires an evaluation of their quality according to standards or specific requirements that are constantly updated in line with scientific and technological progress, emerging issues, and regulatory developments.

This entails a continuous and dynamic revision of the texts that define these rules, followed by their publication in the "reference pharmacopoeia".

TUBE: POLYPROPYLENE

BI-INJECTED CAP: POLYETHYLENE + THERMOPLASTIC VULCANIZATE

STATEMENT ON COMPLIANCE TO REGULATIONS ON MEDICAL USE:

The raw materials used in the production of Biosigma's Cryogen Tubes meet the requirements for materials intended for medical devices, whether finished articles or their components, as described in:

- *European Pharmacopoeia*, 7th edition (2011), and supplement 7.5 (07/2012) - **Monograph 3.2.2. Plastic containers and closures for pharmaceutical use** (Council of Europe);
- *United States Pharmacopoeia*: the product has successfully passed USP testing, including Class VI biological evaluations and has been assigned an **FDA Drug Master File (USA)**.

Additionally, the materials have successfully passed the biological evaluations in accordance with **ISO 10993**, for external communicating devices involving indirect blood contact over an extended period.

ISO 10993:

ISO 10993 is the European standard for the biological evaluation of medical devices and is comparable to the USP approach; however, it is more comprehensive, with a broader range of categories and tests.

The materials used for our CryoGen Tubes are tested for their suitability in the production of external communication devices intended for prolonged use (min 1 day - max 30 days) and involving indirect contact with the path of the blood (e.g., the plastic to produce a catheter tube).

Executed Tests:

- Cytotoxicity
- Sensitization
- Intracutaneous reactivity (irritation)
- Systemic toxicity
- Haemocompatibility

EP - The *European Pharmacopoeia* is a legislative text which includes chapters and monographs to be followed in the production, preparation, and marketing of products intended for pharmaceutical and medical use.

What is meant by "conforms to USP Class VI"

The United States Pharmacopoeia (USP) establishes standards to ensure the quality of medicines and other health care-related technologies.

Among these, there are the Biological Reactivity tests for "*elastomers, plastics and other polymeric material with which the patient may, directly or indirectly come into contact*", which are divided into six classes.

The **Class VI** is the most stringent class, widely used and accepted by the medical products industry.

Depending on the outcome of the analysis, a material can be considered suitable or not for the production of medical devices.

While not required in Europe, the majority of customers appreciate the USP certification.

DMF= Drug Master File

The Drug Master File is a technical document sent by the product manufacturer to the FDA (U.S.) in which are described:

- | | |
|--|------------------------------|
| ▪ Production processes | ▪ Quality System |
| ▪ Commitments by the Director of the plants | ▪ Results of the USP tests |
| ▪ Product specifications (including formulation) | ▪ List of authorized persons |

Once approved, the FDA issues a number of DMF, with which it is registered in the database.

A DMF ensures consistency in formulas and production procedures.

MEDICAL GRADE RAW MATERIALS

OTHER COMPLIANCE:

- **REACH - Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles**
e.g. phthalates, low molecular weight compounds (known as DEHP, DBP, and BBP DIBP) are classified as toxic for breeding based on animal studies and are regulated in their use and included in the annex XIV of the REACH Regulation as "Substances of Very High Concern" (SVHC) and subject to authorization
- **CONEG (packaging and packaging waste - PPW)**
Total concentration of Cd, Cr, Hg and Pb must be <100 ppm
- **Directive 2000/53/EC (ELV)**
Cr(VI), Hg and Pb <0.1% by weight
Cd <0.01% by weight
- **Directive 2011/65/EU - Restriction of use of certain hazardous substances in electrical and electronic equipment and machinery**
ROHS-Cr(VI), Hg, Pb, PBB and PBDE <0.1% by weight
Cd <0.01 % by weight
- **Directive 2002/96/EC - Waste Electrical and Electronic Equipment - WEEE**
Annex II - No ingredients are used requires a selective waste treatment (As, Hg, PCB, PCT, CFC, HCFC, HFC, brominated FR)
- **Regulation 1005/2009/EC - Substances that deplete the ozone layer**
Prohibition of CFC's, HCFC's, Halons, CCl₄, Trichloroethane, HBFC's
- **U.S. Clean Air Act, Title VI, classes I and II (EPA Final Rule, Federal Register 8136, 11.02.1993) on substances that deplete the ozone layer**
- **Regulation 850/2004/EC on persistent organic pollutants (POPs)**
- **Directives 2003/89/EC, 2006/142/EC, 2007/68/EC, amending Directive 2000/13/EC - Annex IIIa (allergens)**

The materials are also declared free of animal products, and pose no potential risk of TSE.

BSE is a chronic, degenerative, and irreversible neurological disease. It belongs to a group of diseases known as TSEs that affect various animal species, including humans.

Search CLEARLine certificates of analysis on:

<https://www.biosigma.com/certificates/>



Certificates

[Search CLEARLine and sterilization certificates](#)

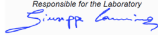
Catalog number Required, Minimum 3 Characters

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Lot number Required, Minimum 3 Characters

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Q Search certificates now

	 21200010344509	BIOSIGMA s.p.a. - Le Diagnostiche Dutchster Company	Modulo: 01 - 0021.01.3 Rev. 2022/04						
Certificato di Analisi / Certificate of Analysis									
	<table><tr><td>Codice Prodotto / Catalogue number :</td><td>CL753/S</td></tr><tr><td>Numero Lotto / Lot Number :</td><td>23P2017200</td></tr><tr><td>Scadenza / Expiry Date :</td><td>2027/05</td></tr></table>			Codice Prodotto / Catalogue number :	CL753/S	Numero Lotto / Lot Number :	23P2017200	Scadenza / Expiry Date :	2027/05
Codice Prodotto / Catalogue number :	CL753/S								
Numero Lotto / Lot Number :	23P2017200								
Scadenza / Expiry Date :	2027/05								
DNase Metodo / Method : Digestione DNA / DNA digestion Limiti / Limit : Non rilevabile / not detectable (LOD 1,5X10⁻⁶ Kunitz-unit)									
RNase Metodo / Method : Digestione RNA / RNA digestion Limiti / Limit : Non rilevabile/not detectable (LOD =1X10⁻⁶ Kunitz-unit)									
Endotossine / Endotoxins Metodo / Method : LAL TEST Cromogenico / Chromogenic LAL TEST Limiti / Limit : < 0.01 EU/ml									
I test del lotto sopra descritto hanno dimostrato la conformità ai limiti di rilevamento. Il lotto viene rilasciato per l'uso. Testing of the above described lot showed conformity within limits of detection. The Lot is released for use.									
I risultati dei test si riferiscono esclusivamente agli articoli testati. The test results refer exclusively to the item tested.									
Dott. Giuseppe Carrinno PhD Responsabile del Laboratorio Responsible for the Laboratory  		Data di Rilascio / Date of release (data release date) (day month year) 23/05/2023 Biosigma s.p.a. - Le Diagnostiche Dutchster Company Via Valfredda, 6 - 20010 Casteneta di Corsa (VE), Italy Tel. +39 0426 302228 Fax +39 0426 302228 Email info@biosigma.com www.biosigma.com Cap. Soc. 30.000 € i.v. (C.F. 01219600281) Biosigma s.p.a. è un'azienda a partecipazione paritetica Biosigma - Dutchster							

ABOUT US

Biosigma was founded in 1988 and is located near Venice. Our headquarters extend over 12,000 square metres, where we produce some of the many items in our catalogues. The production, equipped with sophisticated machinery, innovative automation and two clean rooms, is designed to guarantee products free from human and bacterial DNA, DNases, RNases, bacterial endotoxins, PCR and ATP inhibitors.

Thanks to our advanced computer system, the sales office is able to provide rapid and detailed answers to our customers. Our constant commitment to technological development has allowed Biosigma to offer a service increasingly oriented towards customer satisfaction, with shipments in Italy that are guaranteed delivery times of 3 to 5 days.

Our products are distributed in over 50 countries worldwide, both directly from our warehouses and through our national and international distributors. In August 2011, Dominique Dutscher SAS acquired the majority of our share capital. Dominique Dutscher SAS is a leading French group in the distribution of consumables and equipment for life sciences and biotechnology.

Our website, www.biosigma.com, offers over 100,000 items from more than 140 renowned brands, complete with descriptions and technical sheets. We also offer numerous products on the Mepa portal (Italian online purchases for the public administration).

Biosigma continues to operate under its own name as an independent company, maintaining its philosophy of attentiveness towards customer needs, but benefiting from the strength of a group that possesses one of the largest European stocks of consumables and scientific instrumentation. Our sales network in Italy is made up of young biotechnologists who cover the entire national territory, including its islands. In addition, a director of research is available at the company to answer technical-application questions from customers as is a biologist responsible for the internal laboratory.



The Italian brand synonymous with quality and innovation whilst respecting the environment



Dutscher Europe, the strength of a group

- One of the largest stocks of consumables and scientific instruments in Europe
- A fast, accurate logistics service, suitable for all customers
- A technical-commercial team close to you for advice
- A complete and intuitive catalogue and website, high-performance e-business tools
- Strong values of respect and pursuit of excellence
- Continuous research into new high-quality products



SUSTAINABILITY



Our commitment to sustainable development and environmental protection



Photovoltaic systems

Since 2011, Biosigma has installed a photovoltaic system that now generates 740,000 kWh per year and prevents the emission of 450,000 kg CO₂ per year.



ISO 14001

Biosigma has successfully kept its UNI EN ISO 14001 environmental certification since 2013.



Treedom

Treedom® is the first platform in the world that allows you to plant a tree remotely and follow the history of the project online. Through this platform, Biosigma has already planted 500 trees in different areas of the world.



CONAI

Biosigma is a member of CONAI, a private non-profit consortium created to increase packaging recovery and recycling.



ISCC

Biosigma is ISCC Plus certified, a voluntary process applicable to the bioeconomy and to the circular economy for food, feed, chemical products, plastic, packaging, textile products and renewable raw materials derived from a process that uses sustainable energy sources.



ESG

Biosigma is working to adopt the ESG (Environmental, Social and Governance) criteria; these are three fundamental dimensions to verify, measure and control the Company's commitment to sustainability. This involves adopting measures to reduce pollution, CO₂ emissions and waste. It also means having a diverse and inclusive workforce, from entry into the company to the board of directors.

SUSTAINABILITY PARTNER



Ogyre

We directly support Ogyre in the Fishing for litter project. Ogyre supports fishing communities by providing funding that allows them to recover waste from the sea during normal fishing operations. The waste collected is then gathered, separated and disposed of correctly.



E-Bike

In 2023 we started a sustainability project that provides some e-bikes to employees for home-work travel. The goal is to reduce air pollution and traffic congestion, promoting the culture of sustainable mobility and the use of zero-impact means of transport for daily travel.



Biosigma's internal laboratory guarantees quality control of the items produced and distributed by the company, satisfying rigorous regulatory and internal requirements.

The laboratory manager uses advanced Molecular Biology, Biochemistry and Microbiology methodologies to assess the purity of the products and issue certificates of conformity.

The "quality control" protocols adopted are extremely scrupulous and scientifically validated with stringent parameters, recognised by the international scientific community.

Every production batch undergoes a rigorous sampling and analysis process, ensuring compliance with specific standards and the safety of the production lines.

The strict application of these methods not only allows complying with current regulations, but also forestalling and preventing any non-compliance before distribution.

Thanks to this methodical and rigorous approach, Biosigma ensures the highest quality and safety of its products, confirming its excellence in the sector.

Dr Giuseppe Cannino PhD

CLEARLine is a Biosigma's registered trade mark synonymous of **purity**, **clean** and **safety**.

Our CLEARLine products are ideal for the most sensitive applications, thanks to the use of high-quality raw materials and specific procedures during the production phase. The products are manufactured under strict quality standards and their purity is certified by lot by an external accredited laboratory.



Registered trade mark identifying CLEARLine products manufactured by Biosigma

CLEARLine
Accessories

Registered trade mark identifying accessories for CLEARLine products

ClearLine

Trade mark identifying CLEARLine products distributed by Biosigma



CONTACTS - OUR TEAM



PHONE
+ 39 0426 302226



Biosigma S.p.A.
Via Valletta, 6 - 30010
Cona (Venice) Italy



Phone 0426 302226
8.30-13.00 / 14.00-17.30
Fax 0426 302228



export@biosigmaeu.com



Stefania Pizzeghello
Export Manager

+39 0426 302226 int. 201
✉ spizzeghello@biosigmaeu.com
☎ +39 338 6647513



Alessandra Bolzonaro
International Sales:
East Europe, North America, Australia, France and
Dominique DUTSCHER Interco

+39 0426 302226 int. 244
✉ abolzonaro@biosigmaeu.com
☎ +39 349 6771961



Debora Aggio
Marketing Specialist, International Sales:
North/West Europe, Middle East, Asia, Africa,
Central/South America

+39 0426 302226 int. 269
✉ daggio@biosigmaeu.com
☎ +39 349 8635246

Biosigma adheres to:



**CONFINDUSTRIA
VENETO EST**
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ESBB

European, Middle Eastern
& African Society
for Biopreservation
and Biobanking





INSIDE
FULL SPECIFICATIONS
OPEN HERE



Dominique Dutscher Group
Address: Via Valletta, 6 • 30010, Cona (Venice) Italy

Phone ++39 0426 302226

export@biosigmaeu.com

www.biosigma.com

V.A.T. IT 03328440270

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"Be cool, be safe, be CLEARLine"