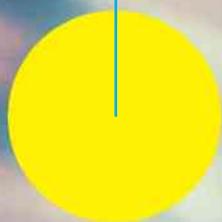
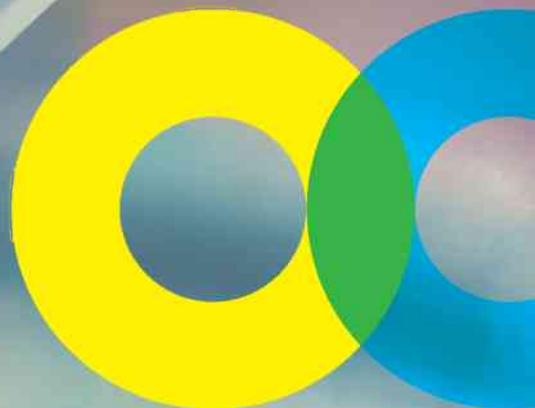
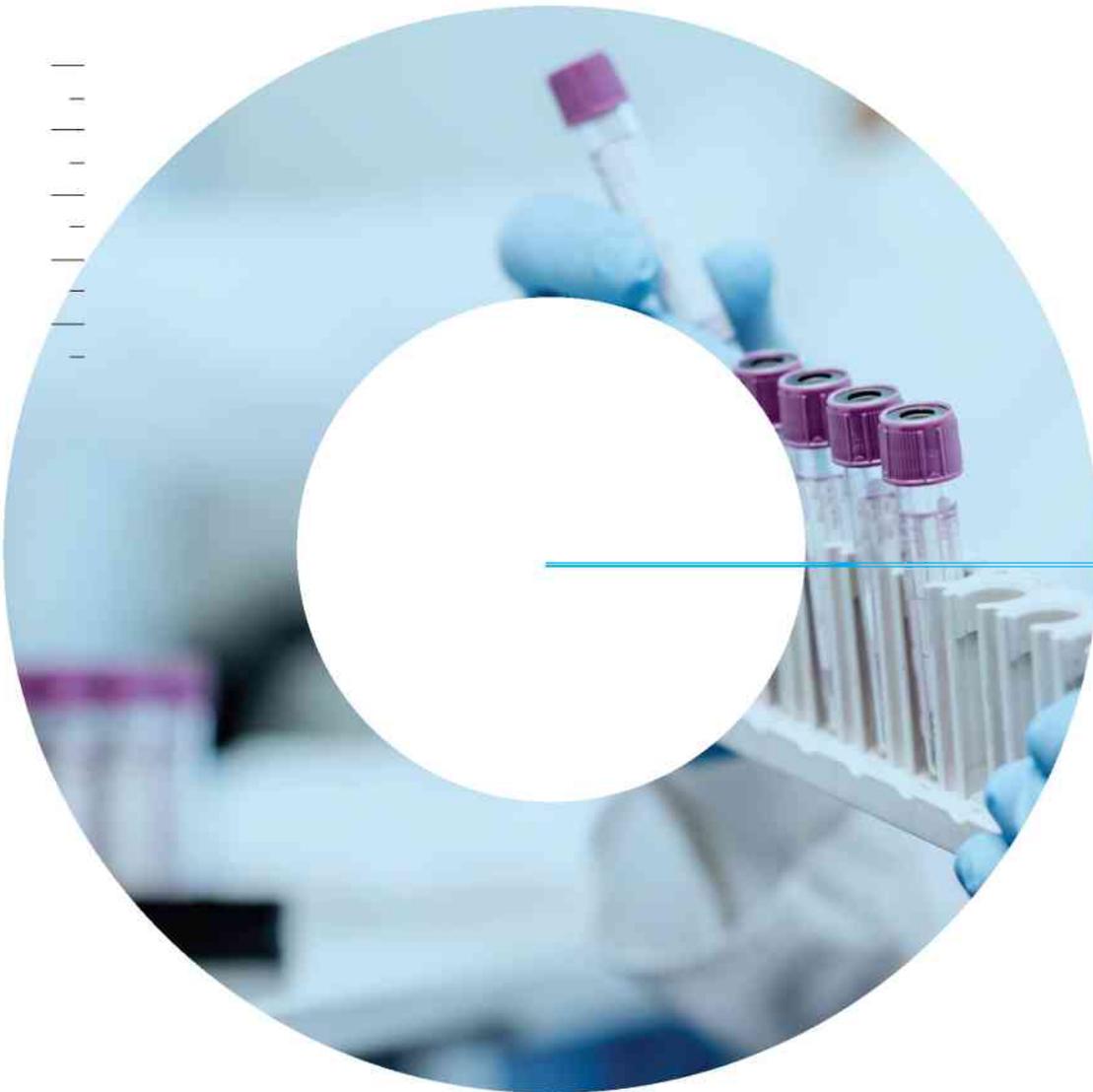




Your needs, our innovations





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Dear customers, distributors, suppliers and friends,

It is again a pleasure to be able to address all of you through this new edition of DELTALAB's Catalogue.

A Catalogue that highlights the work done by our company in these more than 40 years, and that wants to respond to the needs of our customers.

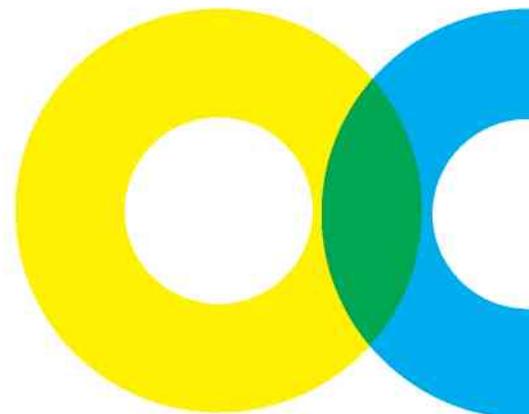
Our well known company philosophy: innovation, quality, service and efficiency, has been and will be always linked to our daily work, with a clear final objective: our customers' satisfaction.

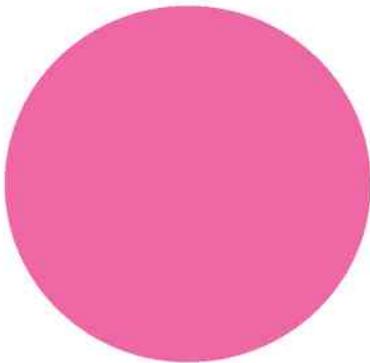
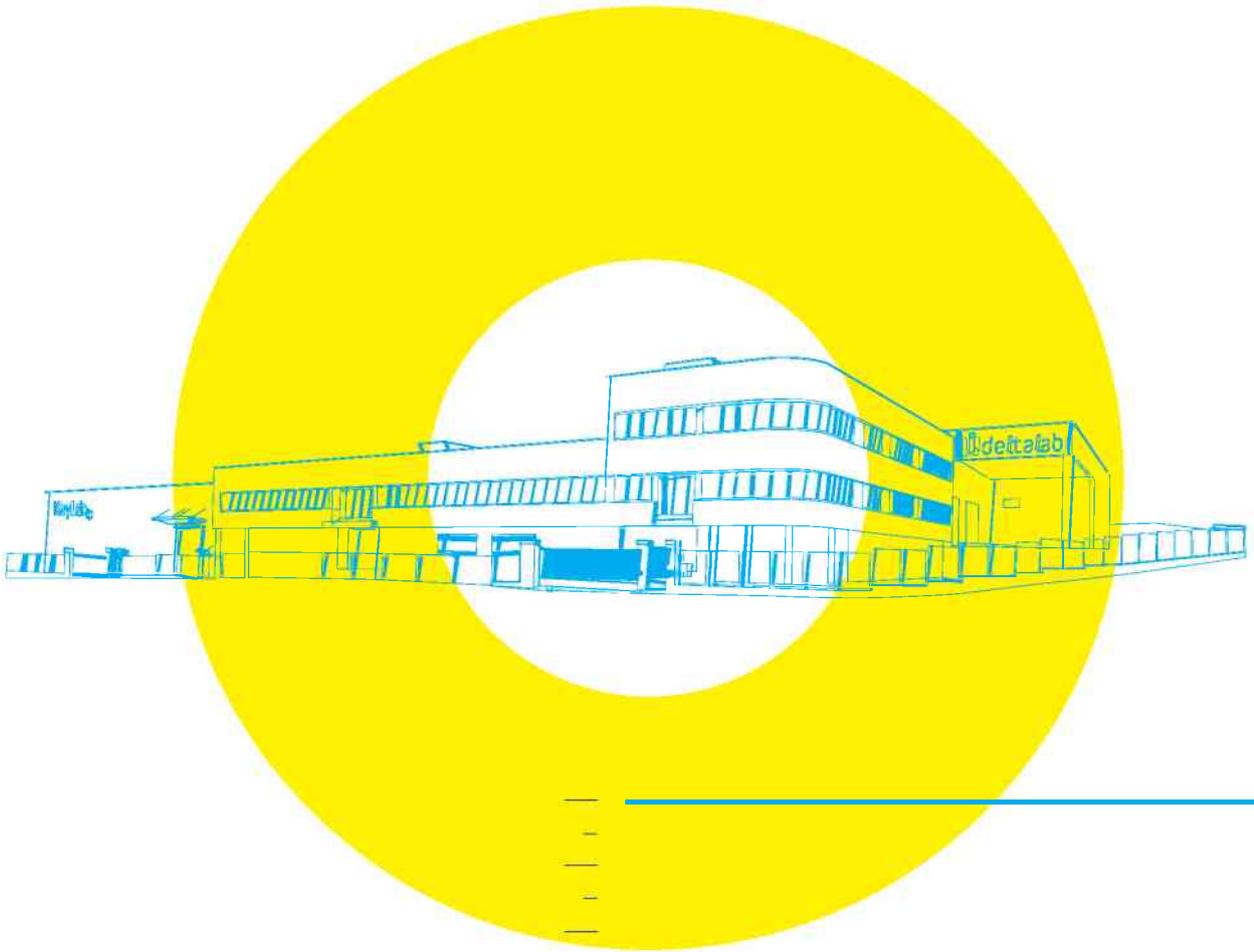
At the doors of the beginning of a new decade our market continues to show solidity, being naturally an evolving market. The increasing automation of processes and the search for higher speed and reliability in diagnosis are clearly influencing the demand for new solutions. Finding the right scale to grow in this new competitive environment, increasing investment in R&D, developing our production and operational processes in search of higher productivity, adapting the forthcoming regulatory changes are some of the challenges that as of today, we are facing them and will be decisive to continue competing for the future of our market.

From Deltalab, we take these new challenges with the same enthusiasm that we have put through all these years, and we will redouble our efforts to continue having the best solutions for our clients. For this, we want to count, as always, with your invaluable collaboration. Your success will be ours too.

We hope that this new edition of our Catalogue will help us to meet our common objectives and be the tool that gives us the key to this near future success.

José Sáez Mateos
CEO





**CERTIFICATIONS OF THE INTEGRATED MANAGEMENT SYSTEM
(quality and environment)**



ISO 9001: 2015
Quality management systems.



ISO 13485:2016
Medical devices.
Quality management systems.
Requirements for regulatory purposes.



ISO 14001: 2015
Environmental management systems

DELTALAB ISO CERTIFICATIONS

Deltalab's Quality Management System is certified as per ISO 9001:2015 and ISO 13485:2016 standards.

Since August 2019, Deltalab has been granted the **ISO 14001:2015 Certification**. This standard ensures that our companies have an Environmental Management System, which allows us to control the environmental impact of our products and activities. Deltalab, being a company **committed with the environment protection**, has decided to implement the mentioned Environmental Management System to reduce as much as possible the environmental impact.

The plastic materials of the products manufactured and commercialized by Deltalab are of high quality and are adequate to the needs of every product. For example, they are suitable for food contact, free of latex and other harmful substances such as heavy metals, phthalates, bisphenol or asbestos. Provided the products made of plastic are not chemically polluted, they are fully recyclable and biodegradable, and must be disposed of following the law in every country.

The packaging cardboard materials used in for the products commercialized by Deltalab are biodegradable and recyclable. To ensure a responsible management of the natural resources, these materials follow the FSC guidelines.

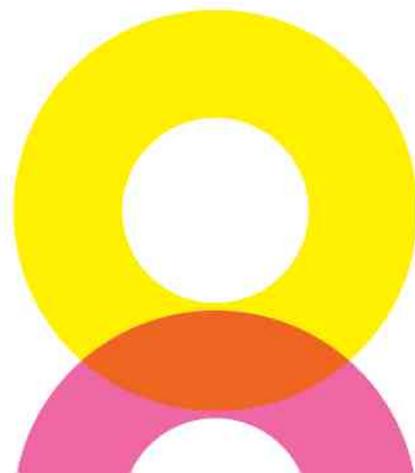
CE MARK OF MEDICAL DEVICES (MD) AND MEDICAL DEVICES FOR IN VITRO DIAGNOSTICS (IVD)

The CE Mark concerns those products that, affecting human beings, may involve a risk to their health. Therefore the CE Mark warrants that a product has been designed and manufactured so that it complies with the following requirements:

- **Does not compromise the health or clinical status of a patient.**
- **Does not endanger the user's health or safety.**
- **Does not compromise the health or safety of third parties.**
- **Minimizes the risk of errors of use thanks to its ergonomic features and the environment in which it is intended to be used.**
- **It takes into account the technical knowledge, expertise, experience, training, and medical and physical conditions of the intended users.**

The CE Mark requires that facilities, work organisation, and systems are subject to rigorous both internal and external quality controls. It also guarantees the highest level of safety when using those products intended for the sample collection and handling of human samples, directly and also for taking human clinical samples and their subsequent in vitro diagnosis.

The CE Mark guarantees that the products will be freely commercialised within the European Union.



1.

MEDICAL DEVICES (MD)

According to Regulation UE N° 2017/745 on Medical Devices (that will replace Directive 93/42/CEE) a Medical Device is any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- Providing information by means of in vitro examination of specimen derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

This Regulation, that will enter into force in May 2020, establishes 4 categories of medical devices, depending on the risk (time of contact and invasivity). DELTALAB manufactures and commercialises products of transient use classified as **Class I (sterile and non-sterile)** and **Class IIa:**



Class I (Non sterile):

Low risk, invasive medical devices

It includes: non sterile tongue depressors, speculums, etc. Inspection gloves are considered both as MD Class I and PPE (Personal Protective Equipment). All of them are self-certification products, so No Notified Body is required.



Class I (sterile):

Low risk, sterile, invasive medical devices

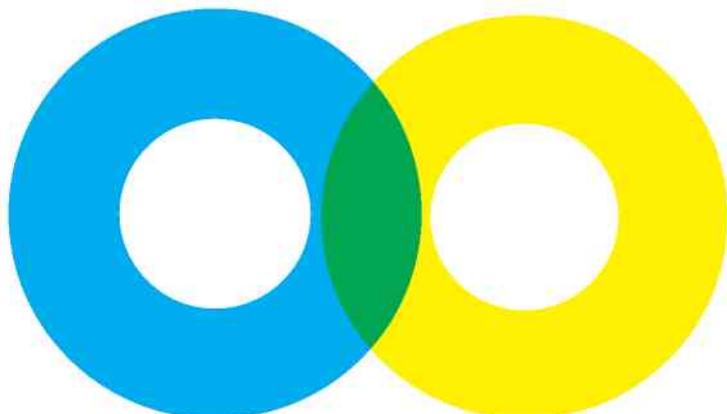
Among others: sterile tongue depressors, sterile Ayre spatulas, sterile cytology brushes, flocked swabs with and without transport media. They are certified by a Notified Body.



Class IIa (sterile):

Moderated risk, sterile surgically invasive medical devices

Swabs with and without medium are included in this Class. They are certified by a Notified Body. **The CE Mark allows these swabs to be used in surgical operations as an invasive product.**



Anticoagulants and preservatives in containers

Available in bottles of 15 ml.

The dosage of one drop (15 ml = 300 drops) is enough for 5 ml of blood.

Both products have preservatives for stability.

Code **705000** composition: lithium heparin, phenylmercury acetate and distilled water. Prepared according ISO 6710. Heparin concentration between 12 and 30 µl for each ml of blood.

Expiry date: 24 months.

code	description	case quantity	case weight	case volume
705000	heparina de litio 15 ml	10	0.29	0.00019



Special techniques

Liquid for thrombocyte count determination:

Due to its optical characteristics it identifies the thrombocyte avoiding confusion with other cells. This reagent also prevents adhesion and aggregation of the thrombocytes. Full instructions are included with the kit.

Test of osmotic brittleness of the erythrocytes:

The test for the erythrocyte osmotic fragility detects the resistance of these cells to haemolysis, in hypotonical solutions with decreasing concentration of sodium chloride.

This set contains 2 complete tests and each one is composed of 12 tubes with stable and buffered solutions. Full instructions are included in the kit.

Expiry date: 24 months.

code	description	case quantity	case weight	case volume
800000	thrombocyte counting kit 1 x 50 tubes	30 kits	5.50	0.045
802000	osmotic brittleness of erythrocytes kit 2 x 12 plus 2 lithium heparine tubes	30 kits	7.50	0.045

Minimum order quantity: 1 kit.



Reticulocyte staining kit

This simple to use kit consists of a tube containing 100 µl of stable buffered bright cresil blue stain which allows the determination of the erythrocyte count.

Two to three drops of blood are added directly to the tube and incubated for 10 minutes at room temperature.

The erythrocytes become a pale blue colour making them easy to identify.

Full instructions are included with the kit.

Tube made of polypropylene and cap of polyethylene.

Expiry date: 24 months.

code	description	case quantity	case weight	case volume
801000	reticulocyte count kit (1 x 50 tubes)	30 kits	5.50	0.046

Minimum order quantity: 1 kit.



Stains

code	description	volume	dangerousness	transport rules		CE certificate	case quantity	case weight	case volume
May Grunwald solution									
808000	Eosin	250 ml	H225, H331, H311, H301, H370	ONU 1992 ADR 3/6 1/II IMDG 3/6 1/II IATA 3/6 1/II PAX 352 CAO 364		CE (IVD)	16	4.80	0.015
808001	Eosin	1,000 ml	H225, H331, H311, H301, H370	ONU 1992 ADR 3/6 1/II IMDG 3/6 1/II IATA 3/6 1/II PAX 352 CAO 364		CE (IVD)	12	13.00	0.045
Giemsa solution									
808100	Eosin	250 ml	H225, H331, H311, H301, H370	ONU 1992 ADR 3/6 1/II IMDG 3/6 1/II IATA 3/6 1/II PAX 352 CAO 364		CE (IVD)	16	5.15	0.015
808101	Eosin	1,000 ml	H225, H331, H311, H301, H370	ONU 1992 ADR 3/6 1/II IMDG 3/6 1/II IATA 3/6 1/II PAX 352 CAO 364		CE (IVD)	12	13.00	0.045
Wright stain									
808200	Eosin	250 ml	H225, H331, H311, H301, H370	ONU 1992 ADR 3/6 1/II IMDG 3/6 1/II IATA 3/6 1/II PAX 352 CAO 364		CE (IVD)	16	4.43	0.015
Gram stain									
Kit 805000	806030	Lugol	250 ml	-	-	-	16	4.90	0.015
	805040	Gentian violet	250 ml	-	-		16	4.80	0.015
	805001	Gram decolorizing	250 ml	-	-		16	4.25	0.015
	805050	Safranin solution	250 ml	H226	ONU 1993 ADR 3/III IMDG 3/ III IATA 3/III		16	4.80	0.015
805001	Gram decolorizing	250 ml	H225, H319, EUH066, H336	ONU 1993 ADR 3/III IMDG 3/III IATA 3/III PAX 353 CAO 364		16	4.25	0.015	
806030	Lugol Iodine	250 ml	H412	-	-	16	4.90	0.015	
805040	Violet crystal solution	250 ml	H302, H351, H318, H410	-		16	4.80	0.015	
805140	Violet crystal solution	1,000 ml	H302, H351, H318, H410	-		12	13.00	0.045	
Ziehl stain									
Kit 805010	805020	Fuchsin	250 ml	-	-		16	4.66	0.015
	805030	Methylene blue	250 ml	-	-		16	4.80	0.015
	805011	Ziehl decolorizing	2 bottles of 250 ml	-	-		16	4.46	0.015
805050	Safranin solution	250 ml	H226	ONU 1993 ADR 3/III IMDG 3/ III IATA 3/III		16	4.80	0.015	
805150	Safranin solution	1,000 ml	H226	ONU 1993 ADR 3/III IMDG 3/ III IATA 3/III		12	13.00	0.045	
805120	Ziehl fuchsin solution	1,000 ml	H225, H312, H302, H319, H315, H341	-		12	13.00	0.045	
805030	Methylene blue	250 ml	H302	-		16	4.80	0.015	
805130	Methylene blue	1,000 ml	H302	-		12	13.00	0.045	
805013	Fast stain for blood extensions, Kit with 2 containers of each type containers stain B	250 ml	-	-	-	CE (IVD)	12 Kits	14.95	0.045

Minimum order quantity: 1 bottle or kit. Check with the commercial department for special transport conditions.



Bouchons polyéthylène

mod.	code	to fit tubes	yellow	natural	brown	malve	blue	green	red	black	bag quantity	bag weight	bag volume
			(to add at the end of the code)										
1	3053	300500, 400500, 300800.2		02	03	08		07	06		2 x 2.000	1.60	0.009
2	3058	300800, 400800, 300800.1, 300400, 400400, 400800.1		02		08	05	07	06	09	2.000	1.76	0.007
3	3071	300700, 301700, 400700, 401700, 300701, serie 300700.6	01	02		08	05	07	06	09	2.000	1.50	0.007
4	3072	300705, 300900, 400705, 400900, 401100, 300707		02			05	07	06		2.500	3.00	0.018
5	3050	300705, 300900, 400705, 400900, 401100, 300907, 300904, 300908		02		08		07			2.500	3.26	0.019
6	3081	300705, 300900, 400705, 400900, 401100, 300707, 300907, 300904, 300908		02				07	06		2.500	5.00	0.023
7	3070	300100							06		1.000	1.20	0.012
8	3055	301201, 401201, 301200, 401200, 301202, 401204		02				07			2.500	4.00	0.018
9	3082	301201, 401201, 401204		02			05				2.500	5.10	0.023
10	3066	301213, 301212	01								1.500	1.28	0.012

Ask for other colours.



mod.	code	tubes recommandés	colour	bag quantity	bag weight	bag volume
NEW 11	705722	300705, 300900, 400705, 400900, 401100	red	1.000	1,08	0,096
NEW 12	701061	300800, 300801	green	1.000	0,70	0,003
NEW 13	701034	300300	natural	1.000	0,66	0,003
NEW 14	705595	300500, 300800.2	red	1.000	0,70	0,003

Ask for other colours.



Re-caps

Ideal for re-capping blood collection tubes «vacuum type». Suitable for other glass and plastic tubes. Manufactured in flexible polyethylene. Easy to cap and remove.

Please find racks for these tubes on chapter **Sample Storage**



code	description	quantité par carton	poids du carton	volume du carton
308502	Ø 12-13 mm natural colour	6 x 1,000	1.70	0.025
308506	Ø 12-13 mm red colour	6 x 1,000	2.18	0.025
308602	Ø 15,2-16 mm natural colour	6 x 1,000	1.70	0.025
308606	Ø 15,2-16 mm red colour	6 x 1,000	2.18	0.025

Other colours available on request, minimum order quantity is 6.000 units.

