

Amies. Sterile

AMIES media is a modification of Cary Blair media, which is at the same time a modification of Stuart media. Basically the glycerophosphate is replaced by an inorganic phosphate, and the methylene blue by pharmacological charcoal. Calcium and magnesium are also added, thus maintaining the permeability of the bacterial cell. This media assures the viability of organisms such as:

- Neisseria sp.
- Haemophilus sp.
- Corynebacterium sp.
- Trichomonas vaginalis
- Streptococcus pyogenes
- Streptococcus pneumoniae
- Shigella flexneri
- Salmonella typhi
- Brucella abortus
- Enterobacterias, etc.

The presence of charcoal on the media neutralises inhibitors and bacterial toxins, and improves the recovery ratio of Neisseria gonorrhoeae and Vibrio cholerae

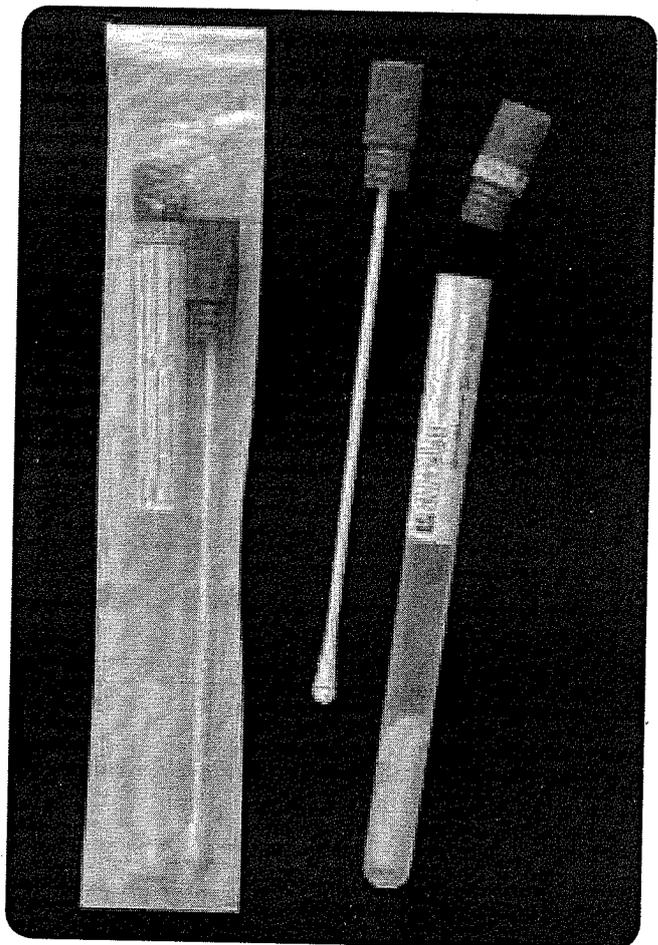
Some microorganisms can resist on the media for up to 3 days, although the recovery of microorganisms is better if cultured in the first 24 hours. Amies transport swabs are available with or without charcoal.

Swabs are sterilised by radiation.

Peel-pack dimensions: 38 x 210 mm. Expiry date: 30 months after sterilisation date.

code	description	case quantity	case weight	case volume
300287	snappable polystyrene + viscose	6 x 100	9.33	0.060
300285	snappable polystyrene + viscose (with charcoal)	6 x 100	9.37	0.058
300281	aluminum + viscose	6 x 100	9.08	0.056
300281/1	aluminum + viscose (with charcoal)	6 x 100	9.15	0.052
300281T	twisted aluminum + viscose	6 x 90	8.24	0.057

Cases per pallet: 32.



Liquid Amies. Sterile

This is a variation of the traditional Amies media swab where the media is presented on liquid form without agar.

Suitable for conservation of pathogens such as:

- Haemophilus sp.
- Corynebacterium sp.
- Trichomonas vaginalis
- Streptococcus pyogenes
- Streptococcus pneumoniae
- Shigella flexneri
- Salmonella typhi
- Brucella abortus
- Staphylococcus epidermidis
- Escherichia coli, etc.

Media is supplied in its liquid form, in a sponge, suitable for direct extensions on slides.

Swabs are sterilised by radiation.

Peel-pack dimensions: 38 x 210 mm.

Expiry date: 30 months after sterilisation date.

code	description	case quantity	case weight	case volume
300284	snappable polystyrene + viscose	6 x 100	7.60	0.055

Cases per pallet: 32.



LMS-Swab Cary Blair

Test tube with green screw cap containing 2ml of liquid CARY BLAIR medium for fecal or rectal clinical samples and for preservation of enteric pathogen agents. PU = 100 pcs/box, 600 pcs/carton

Item	Description	MOQ
• Flocked swab		
1020230	standard tip	600 pcs/carton
1020234	fine tip	600 pcs/carton
1020238	paediatric tip	600 pcs/carton
• Foam swab		
1020231	standard tip	600 pcs/carton
1020235	fine tip	600 pcs/carton
• Dacron swab		
1020232	standard tip	600 pcs/carton

LMS-Swab Selenite

Test tube with white screw cap containing 2ml of liquid SELENITE medium for fecal or rectal clinical samples developed for transportation, survival and isolation of salmonella enterica and shigella sonnei. Reducing the growth of other enteric pathogens like e. coli and fecal streptococci. PU = 100 pcs/box, 600 pcs/carton

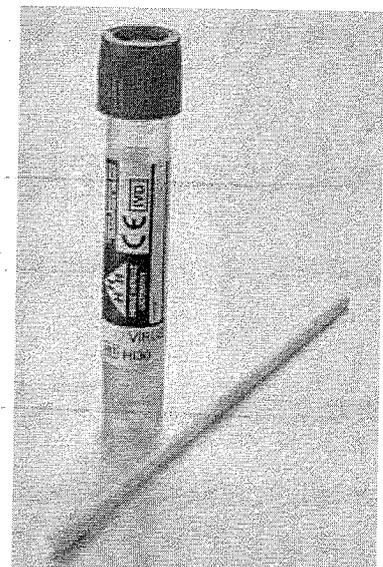
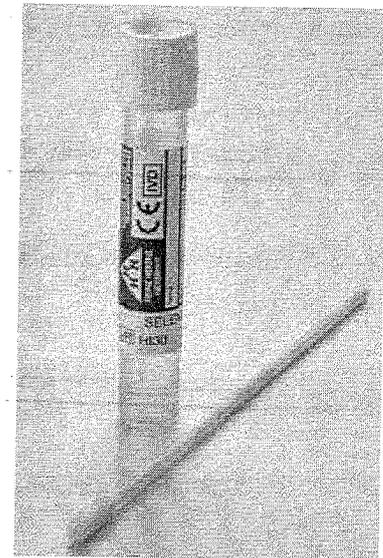
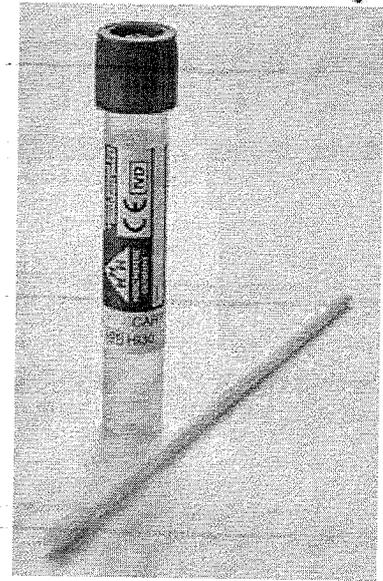
Item	Description	MOQ
• Flocked swab		
1020281	standard tip	600 pcs/carton
1020285	fine tip	600 pcs/carton
1020289	paediatric tip	600 pcs/carton
• Foam swab		
1020282	standard tip	600 pcs/carton
1020286	fine tip	600 pcs/carton
• Dacron swab		
1020283	standard tip	600 pcs/carton

VIR-Swab Virus

Test tube with red screw cap containing 1ml of liquid transport medium developed for the collection, transportation and survival of viruses, chlamydia, mycoplasma and ureaplasma.

PU = 100 pcs/box, 600 pcs/carton

Item	Description	MOQ
• Flocked swab		
13.5 1020240	standard tip	600 pcs/carton
1020241	fine tip	600 pcs/carton
13.4 1020242	paediatric tip	600 pcs/carton
• Foam swab		
1020243	standard tip	600 pcs/carton
1020244	fine tip	600 pcs/carton
• Dacron swab		
1020246	standard tip	600 pcs/carton
• Viscose/rayon swab		
1020245	plastic stick, fine tip	600 pcs/carton
1020247	aluminium stick, fine tip	600 pcs/carton

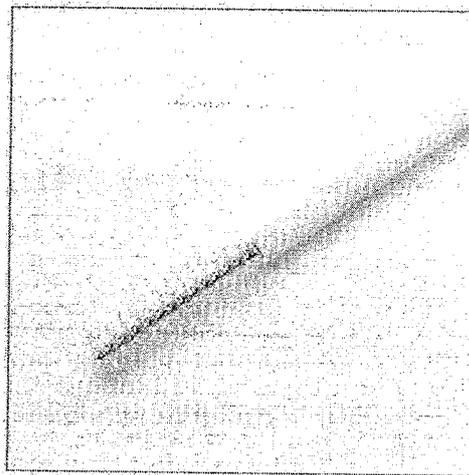


Spazzolino endocervicale KITO BRUSH

CE

Spazzolini per il prelievo endocervicale, per citologia e microbiologia
Small brushes for endocervical samples, for use in cytology and microbiology

Cod.	Descrizione Description	Q.tà Qty
0810	KITO-BRUSH-bulk	100 pcs
0640	KITO-BRUSH sterile in confezione singola sterile single packed	500 pcs
0811	KITO-BRUSH tipo "profile"	100 pcs

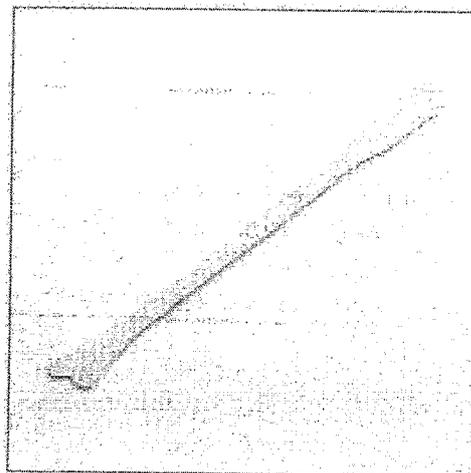


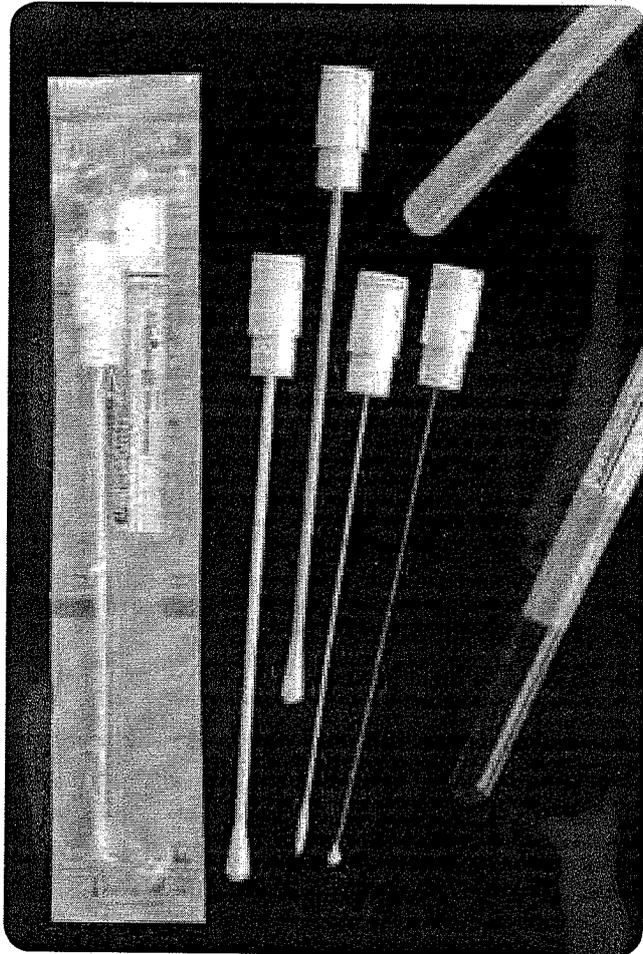
Spatole di Ayre Ayre scraper

CE

Spatole per prelievo citologico. Realizzate in legno di betulla con bordi arrotondati.
Ayre scraper is specifically designed to collect cytology specimens from the cervix

Cod.	Descrizione Description	Q.tà Qty
0433	spatola Ayre legno wooden Ayre scraper	500 pcs
0877	spatola Ayre legno sterile in confezione singola sterile single packed wooden Ayre scraper	500 pcs
0908	spatola Ayre plastica plastic Ayre scraper	500 pcs
1014	spatola Ayre plastica sterile in confezione singola sterile sterile single packed plastic Ayre scraper	500 pcs





Stuart swabs. Sterile

The modified Stuart media allows the conservation and transportation of a large number of pathological microorganisms, such as:

- Neisseria gonorrhoeae
- Haemophilus influenzae
- Neisseria meningitidis
- Bordetella pertusis
- Corynebacterium diptheriae
- Trichomonas vaginalis
- Staphylococcus aureus
- Streptococcus sp.
- Salmonella sp.
- Shigella sp.
- etc.

The most unstable organisms will remain viable for up to 24 hours and other for several days. The media is reduced due to the presence of thioglycolate, which difficults the enzymatic reactions of the bacteria.

The multiplication of the bacteria is prevented due to the lack of nitrogen in the media.

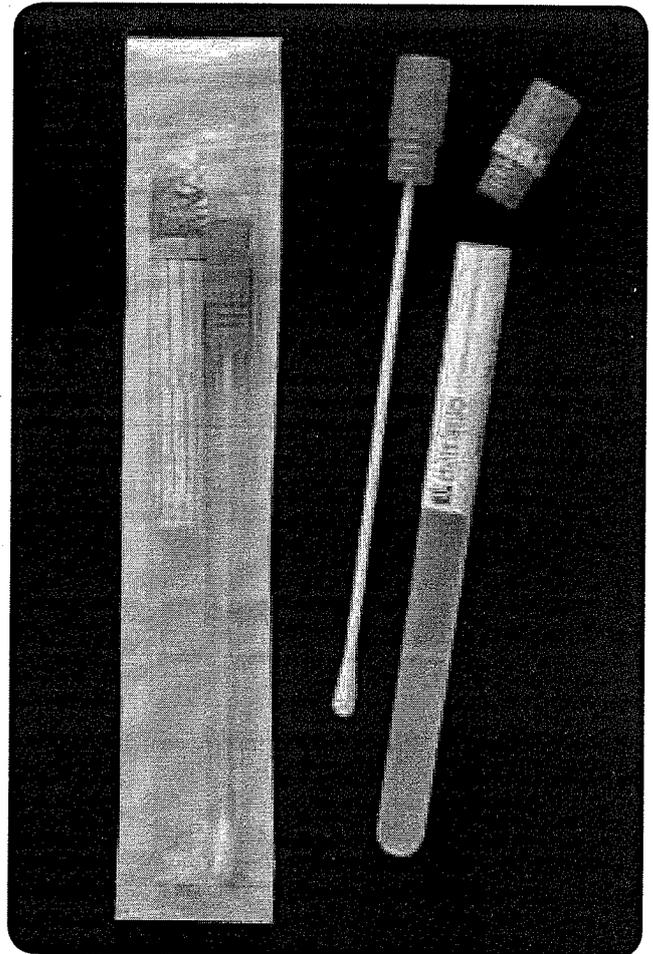
Swabs are **sterilised by radiation**.

Dimensions of the peel-pack: 38 x 210 mm.

Expiry date: 30 months from sterilisation date.

code	description	case quantity	case weight	case volume
300290	wood + cotton	6 x 100	9.40	0.057
300291	aluminium + cotton	6 x 100	9.10	0.057
300295	snappable polystyrene + viscose	6 x 100	8.65	0.060

Cases per pallet: 32.



Cary Blair. Sterile

Cary Blair is another modification of Stuart media.

The glycerophosphate has been substituted by inorganic phosphate since glycerophosphate is a metabolite for some bacteria, so they could grow and disperse the pathogens amount.

The methylene blue has also been removed and the pH increased to 8.4.

This is a media originally developed for faecal samples but is also used successfully for anaerobic transport, such as:

- Neisseria gonorrhoeae
- Vibrio cholerae
- Vibrio parahaemolyticus
- Haemophilus influenzae
- Neisseria meningitidis
- Bordetella pertusis
- Streptococcus pneumoniae
- Shigella flexneri
- Pasteurella pestis
- Campylobacter Spp., etc.

Swabs are **sterilised by radiation**.

Dimensions of the peel-pack: 38 x 210 mm.

Expiry date: 30 months from sterilisation date.

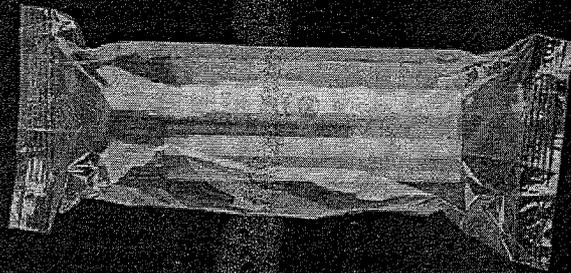
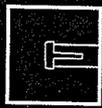
code	description	case quantity	case weight	case volume
300280	wood + cotton	6 x 100	8.50	0.052
300280.2	snappable polystyrene + viscose	6 x 100	8.50	0.056

Cases per pallet: 32.

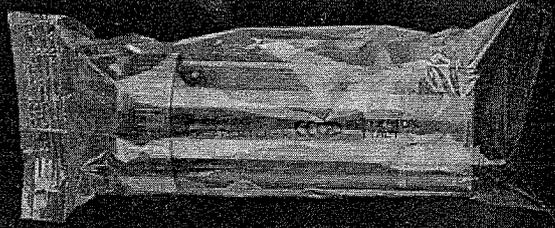
COPROCHAIN®

Faeces containers 30 mL

Frasco 30 mL para heces / Pot 30 mL pour selles / Contenitori feci 30 mL



30 mL



25132

faeces container with frosted label
frasco para heces con banda mate / pot pour selles avec surface
d'écriture / contenitore per feci con superficie di scrittura
individually wrapped, produced in cleanroom ISO 8
en bolsa individual, producido en cleanroom ISO 8 /
emballage individuel produit en cleanroom ISO 8 /
singola prodotto in camera bianca ISO 8



PP

polypropylene / polipropileno / polypropylène / polipropilene

with screw cap
con tapón roscado / avec bouchon à vis / jointe / con tappo a vite



red
rojo / rouge / rosso

25135

faeces container with frosted label
frasco para heces con banda mate / pot pour selles avec surface
d'écriture / contenitore per feci con superficie di scrittura
individually wrapped, sterile
en bolsa individual, estéril / emballage individuel, stérile /
confezione singola, sterile



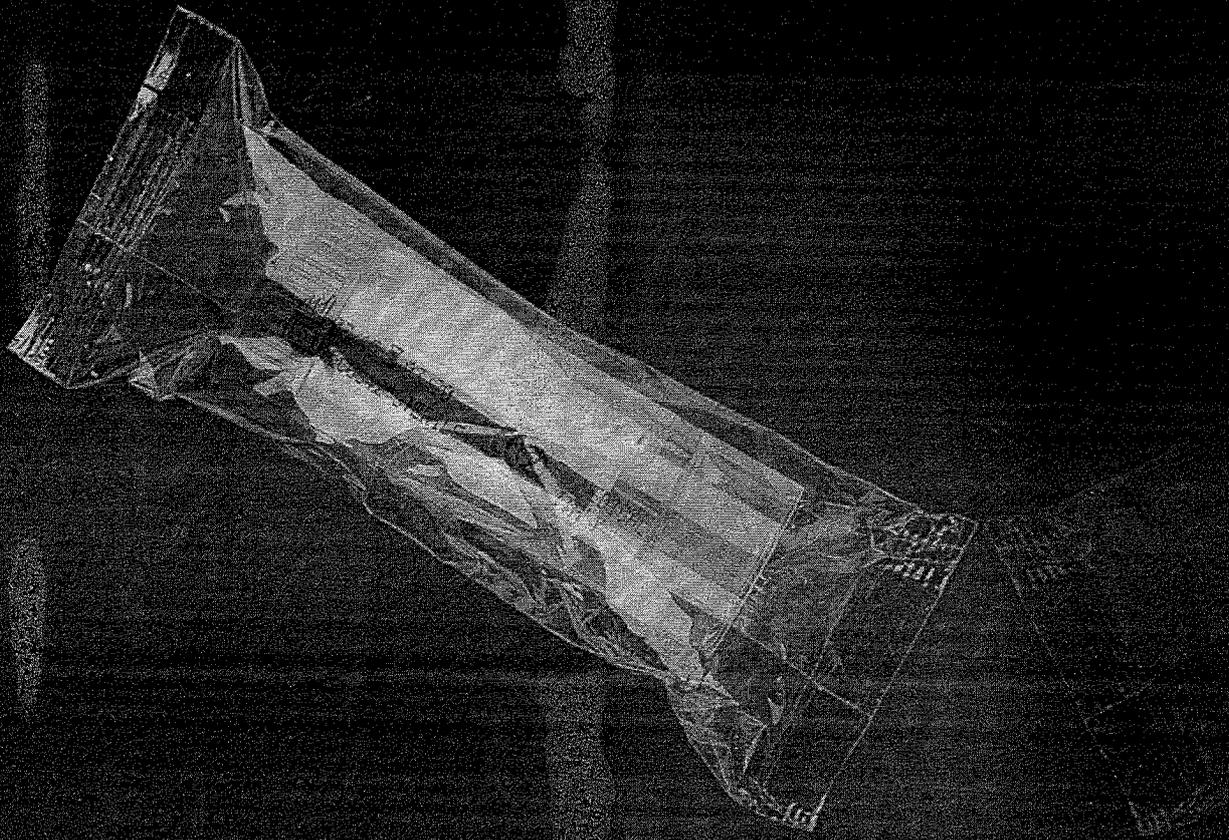
PP

polypropylene / polipropileno / polypropylène / polipropilene

with screw cap
con tapón roscado / avec bouchon à vis / jointe / con tappo a vite

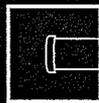


red
rojo / rouge / rosso

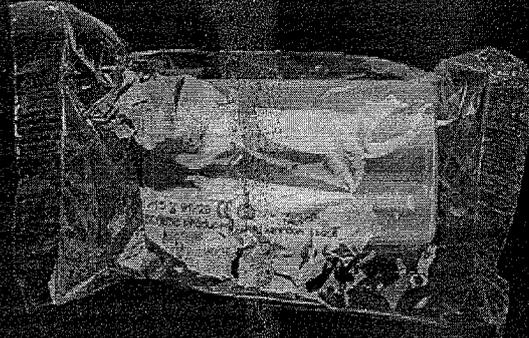
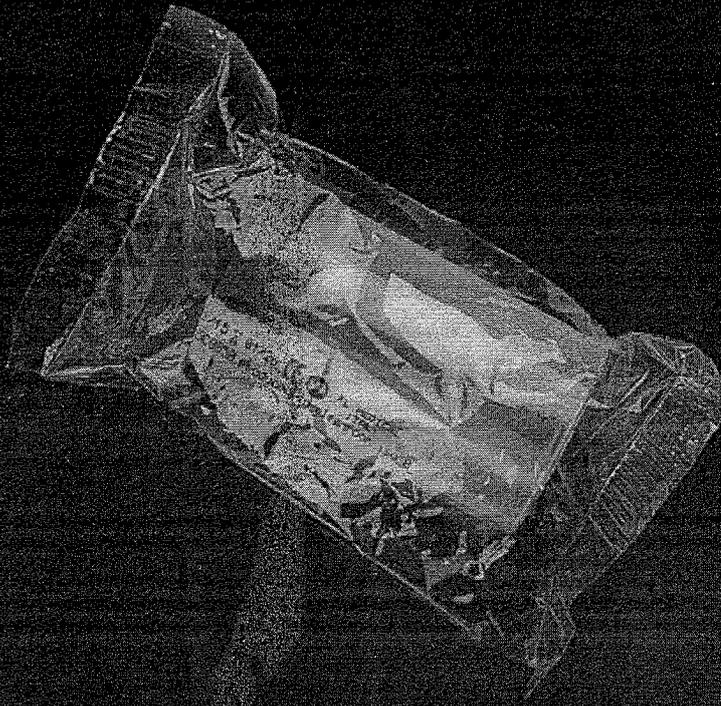


Urine containers 60 mL

Frascos 60 mL para orina / Pots 60 mL pour urine / Contenitori urina 60 mL



60 mL



25182

urine container with frosted label
frasco para orina con banda mate / pot pour urine avec
surface d'écriture / contenitore per urina con superficie di
scrittura



individually wrapped, produced in cleanroom ISO 8
en bolsa individual, producido en cleanroom ISO 8 /
emballage individuel produit en cleanroom ISO 8 / confezione
singola prodotto in camera bianca ISO 8



polypropylene /
polipropileno / polypropylène / polipropilene

with screw cap
con tappo rosado / avec bouchon à vis / con tappo a vite



red
rojo / rouge / rosso

25185

urine container with frosted label
frasco para orina con banda mate / pot pour urine avec
surface d'écriture / contenitore per urina con superficie di
scrittura



individually wrapped, sterile
en bolsa individual, estéril / emballage individuel, stérile /
confezione singola, sterile

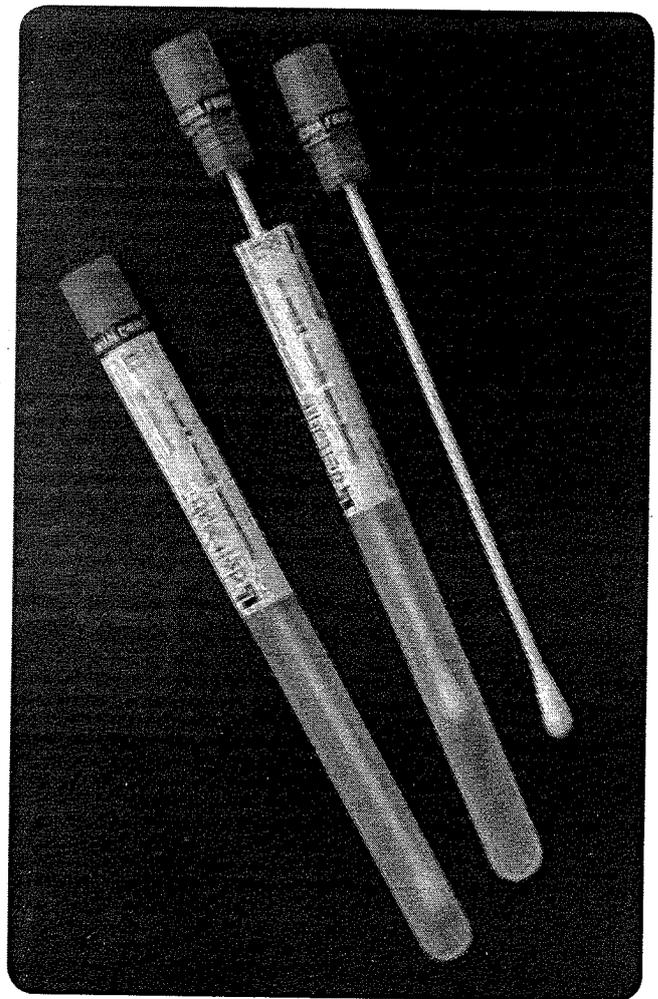
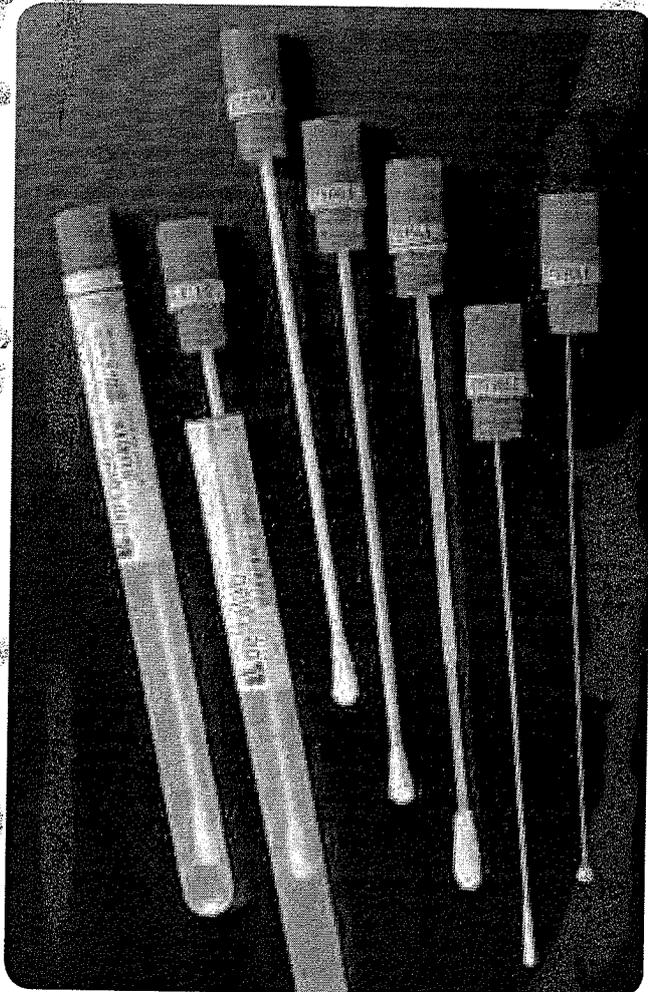


polypropylene /
polipropileno / polypropylène / polipropilene

with screw cap
con tappo rosado / avec bouchon à vis / con tappo a vite



red
rojo / rouge / rosso



Sterile swab in round tube

Sterile dry swabs supplied in shockproof round bottom polypropylene tube, with a label sealing the cap.

Dimensions of tube: Ø 13 x 165 mm.

Sterilised by ethylene oxide.

code	description	case quantity	case weight	case volume	cases per pallet
300250	wood + cotton	4 x 500	14.76	0.060	24
300259	wood + viscose	4 x 500	14.00	0.070	24
300261	snappable polystyrene + cotton	4 x 500	14.90	0.070	24
300252	snappable polystyrene + viscose	4 x 500	15.00	0.066	24
300251	aluminium + cotton	4 x 500	15.00	0.066	24
300253	aluminium + viscose	4 x 500	13.90	0.070	24
300263	snappable polystyrene + polyester	4 x 500	15.00	0.062	24
300250.1	wood + pure cotton	4 x 500	14.00	0.070	24
300254	twisted aluminium + viscose	4 x 500	13.90	0.070	24
300265*	polystyrene + flocked polyester	4 x 500	14.20	0.065	24

Expiry date: 48 month from sterilization date.

*Code not available for sale in Italy.

Twisted aluminium: This is a material exceptionally flexible to use it in sensitive zones as nasopharyngeal, ocular or for pediatric uses.

Flocked polyester: material with high absorbency and overall sample elution.

Human DNAse, RNAse and DNA free certified swabs, steriles

Human DNA free Certified. **Sterilised by ethylene oxyde.**

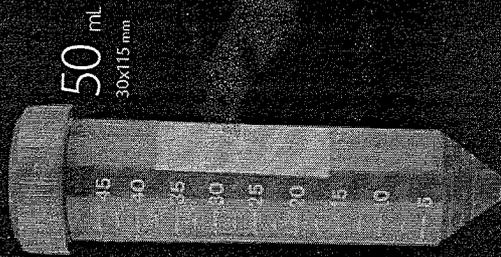
The swab is supplied in a polypropylene tube, which protects the sample up to the laboratory prior to its analysis. The stick of the swab is made of polystyrene while the head is produced with viscose or polyester according to the code. The tube is labeled indicating code, description, lot, expiry date and providing an identifying area to note down collection details (site; date, etc.). Moreover, the label seals the tube with the cap of the swab, acting like a tamper evident system.

code	description	selling unit	case quantity	case weight	case volume
300252DNA	polystyrene + viscose	500	4 x 500	14.20	0.070
300263DNA	polystyrene + polyester	500	4 x 500	14.20	0.070

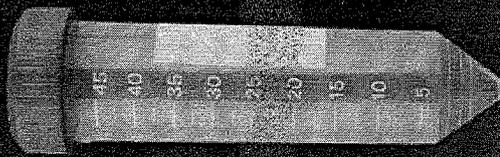
Expiry date: 48 months from sterilisation date



Centrifuge test tubes
Tubos para centrifuga / Tubes centrifugeable / Provette per centrifuga



50 mL
30x115 mm



50 mL
30x115 mm



50 mL
30x115 mm

	test tube conical tubo cónico / tube conique / provetta conica
	graduated graduado / gradué / graduata
	with writing area banda mate / surface d'écriture / superficie di scrittura
	sterile estéril / stérile / sterile
	individually wrapped embalado individualmente / sachet unitaire / confezione singola
	polypropylene polipropileno / polypropylène / polipropilene
	screw cap tapa de rosca / bouchon à vis / tappo a vite
	red rojo / rouge / rosso

21401

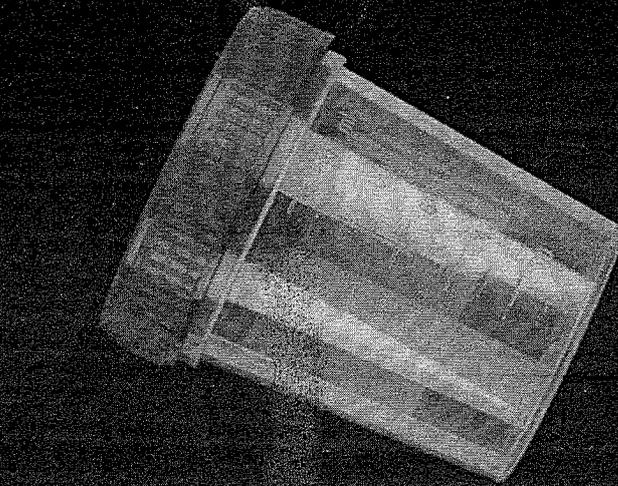
	test tube conical tubo cónico / tube conique / provetta conica
	graduated graduado / gradué / graduata
	with writing area banda mate / surface d'écriture / superficie di scrittura
	polypropylene polipropileno / polypropylène / polipropilene
	screw cap tapa de rosca / bouchon à vis / tappo a vite
	light blue azul / bleu clair / azzurro

21402

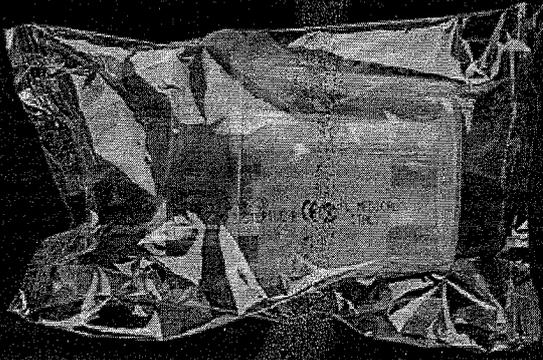
	test tube conical tubo cónico / tube conique / provetta conica
	graduated graduado / gradué / graduata
	with writing area banda mate / surface d'écriture / superficie di scrittura
	sterile estéril / stérile / sterile
	polypropylene polipropileno / polypropylène / polipropilene
	screw cap tapa de rosca / bouchon à vis / tappo a vite
	red rojo / rouge / rosso

Urine containers 120 mL

Frascos 120 mL para orina / Pots 120 mL pour urine / Contenitori urina 120 mL



120 mL



25032

urine container with frosted label
frasco para orina con banda mate / pot pour urine avec
surface d'écriture / contenitore per urina con superficie di
scrittura



individually wrapped, produced in cleanroom ISO 8
en bolsa individual, producido en cleanroom ISO 8 / confezione
singola prodotta in camera bianca ISO 8

polypropylene
polipropileno / polypropylène / polipropilene

with screw cap
con tapón rosado / avec bouchon à vis jointé / con tappo a
vite



red
rojo / rouge / rosso

25035

urine container with frosted label
frasco para orina con banda mate / pot pour urine avec surface
d'écriture / contenitore per urina con superficie di scrittura



sterile
estéril / asepté / a sterile
individually wrapped
en bolsa individual / emballage individuel / confezione singola

polypropylene
polipropileno / polypropylène / polipropilene

with screw cap
con tapón rosado / avec bouchon à vis jointé / con tappo a
vite



red
rojo / rouge / rosso

Urine Monovette®

Efficient sample processing in your urine laboratory

Blood Collection and Diagnostic Products



NEW

NEW

NEW

NEW

Urine Monovette® for hygienic urine collection, transport and analysis

Three functions combined in one product:

1. Hygienic urine collection

Urine can be collected from a sample container by connecting the suction tip and withdrawing the piston

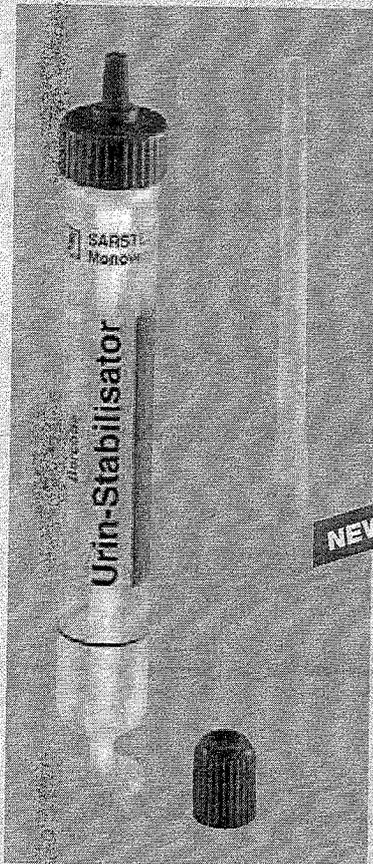
2. Vessel for test strips

The test strip, e.g. Combur9-test, can be immersed directly into the filled Urine Monovette® for urine analysis

3. Centrifuge tube for sedimentation

The Urine Monovette® can be placed into a centrifuge for sedimentation

Volume ml	Order Number	Tube Length/ Ø in mm	Description	Packaging Pcs./Case
8.5	10.258	92/15	-	500
10	10.252	102/15	-	500
10	10.252.001	102/15	paper label	500
10	10.252.030	102/15	white, UV light protection	500
10	10.252.020	102/15	ind. wrapped, sterile	500
10	10.252.015	102/15	50 pieces sub-packaged	500



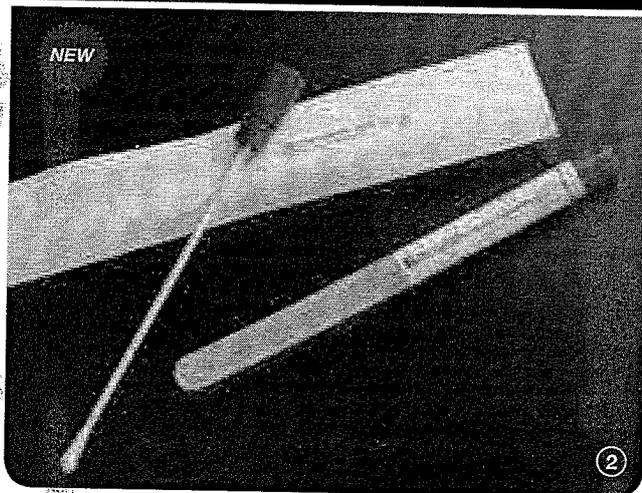
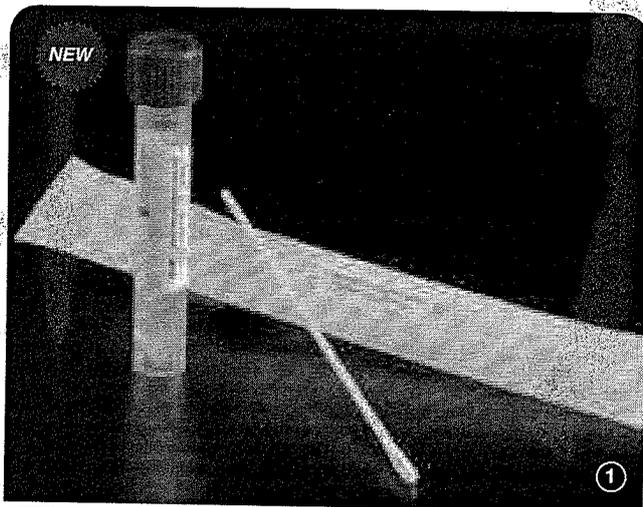
NEW

Urine Monovette® with stabiliser

for bacteriological urine analysis

- The Urine Monovette® prepared with boric acid effectively stabilises micro organisms from sample collection to analysis
- The bacteriostatic effect of boric acid on the most important causes of urinary tract infections has been proven
- Urine collection and sample transport in one container

Volume ml	Order Number	Tube Length/ Ø in mm	Description	Packaging Pcs./Case
10	10.253	102/15	-	500
10	10.253.001	102/15	paper label	500
10	10.253.020	102/15	ind. wrapped, sterile	500



Surface Kit

The new surface kits are supplied with a swab and a tube containing a buffered broth with neutralising agents.

Kits are intended for surface sampling for subsequent microbiological analysis.

The kit is a single use product and is **sterilised by radiation**.

The swab is composed of a polystyrene support with a breakpoint (only reference **200398**) and a viscoscope tip.

The tube incorporates a pressure or screwed cap.

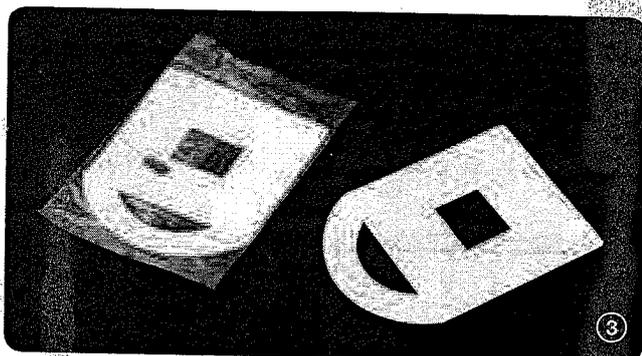
The kit is intended to be used by skilled personnel, properly trained in surface sampling.

The kit is presented individually wrapped in a peel-pack format.

The kit is complemented with the sampling template (**200396P**).

It has a hole of 4x5 cm to perform the sampling, is **sterile** and its supplied in a flow-pack.

mod.	code	description	esterile	case quantity	case weight	case volume
1	200398	10 ml neutralising broth in skirted tube + viscoscope swab	STERILE	6x80	10.30	0.0560
2	200399	5 ml neutralising broth in non skirted tube + viscoscope swab	STERILE	6x100	10.26	0.0560
3	200396P	Surface sampling template 4x5 cm	STERILE	20	0.75	0.0015



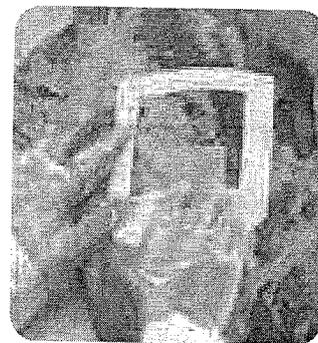
Meat sampling kit

Designed according to the international standard **ISO 17604**, which is taken as reference on European Directives and Rules about microbiology of food and animal feeding stuff – carcass sampling for microbiological analysis.

The kit includes:

- A bottle containing 25ml of sterile buffered peptone water
- A disposable sterile template, supplied in a flow pack bag
- A sponge

code	packaging	esterile	case quantity	case weight	case volume
200393.V	carcass sampling kit with sponge	STERILE	20	3.00	0.025
200393P	template meat sampling	STERILE	20	0.75	0.0051



**DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY**

El fabricante / *The manufacturer.*

DELTALAB S.L.
Plaza de la Verneda, 1
Pol. Ind. La Llana
08191 RUBI (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:
Declares under its responsibility that the product:

**SISTEMA INVASIVO ESTÉRIL DE TOMA DE MUESTRAS CON Y SIN MEDIO DE
TRANSPORTE MARCA EUROTUBO**
**INVASIVE STERILE EUROTUBO COLLECTION SWAB FOR SAMPLE COLLECTION WITH
AND WITHOUT TRANSPORT MEDIUM**
(Códigos según Anexo 1 / *Codes in Annex 1*)

Tipo: Sistema invasivo estéril de recogida de muestras por contacto directo con el paciente.
Type: Invasive sterile collection system by direct contact with the patient

Finalidad Prevista: Recogida y transporte de muestras biológicas para posteriores análisis microbiológicos.
Intended Use: Collection and transport of biological samples for subsequent microbiological analysis

Código GMDN / GMDN Code: 33722

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

ESCOBILLON - Swab

Directiva 93/42/CEE Directiva Productos Sanitarios.
Transposición a la legislación española en Real Decreto 1591/2009.
Directive 93/42/EEC Medical Devices Directive.
Transposition to Spanish legislation in Real Decreto 1591/2009.

Clasificación: Clase IIa
Classification: Class IIa

INFORMACIÓN ADICIONAL

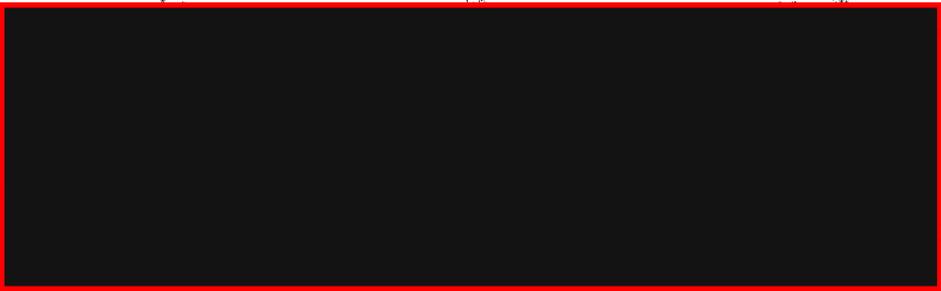
En referencia a los escobillones, este documento tiene su apoyo en el Certificado CE número 2005 06 0474 CP Epigrafe 1, de Garantía de Calidad de la Producción de acuerdo con los Anexos V y VII de la Directiva 93/42/CEE, emitido por la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Organismo Notificado número 0318.

OTHER INFORMATION:

Regarding the swabs, this documentation is supported by the CE Certificate number 2005 06 0474 CP Epigraph 1, Production Quality Assurance according to Annexes V and VII of Directive 93/42/EEC issued by the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Notified Body number 0318.

TUBO CON MEDIO DE TRANSPORTE – Tube with transport medium

Directiva 98/79/CE Directiva Productos Sanitarios para Diagnóstico In Vitro.
Transposición a la legislación española en Real Decreto 1662/2000.
Directive 98/79/EC In vitro Diagnostic Medical Devices Directive.
Transposition to Spanish legislation in Real Decreto 1662/2000.



Jos
Dire

Director

ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

REF	DESCRIPCIÓN	DESCRIPTION
300200	ESCOBILLON MAD.+ALGODON PEEL/1	SWAB I/W PEEL/1 WOOD+COTTON
300201	ESCOBILLON PS+ALGODON PEEL/1	SWAB I/W PEEL/1 PS+COTTON
300202	ESCOBILLON PS+VISCOSA PEEL/1	SWAB I/W PEEL/1 PS+VISCOSE
300203	ESCOBILLON ALU+ALGODON PEEL	SWAB I/W PEEL ALUM+COTTON
300210	ESCOBILLON MAD.+ALGOD.B/2 PEEL	SWAB B/2 PEEL/2 WOOD+COTTON
300250	ESCOBILLON MAD.+ALGODON TUBO	SWAB IN TUBE WOOD+COTTON
300251	ESCOBILLON ALU.+ALGODON TUBO	SWAB IN TUBE ALUM+COTTON
300252	ESCOBILLON PS+VISCOSA TUBO	SWAB IN TUBE PS+VISCOSE
300253	ESCOBILLON ALU.+VISCOSA TUBO	SWAB IN TUBE ALUM+VISCOSE
300254	ESC.ALUM.TRENZADO+VISCOSA TUBO	SWAB TWISTED ALUM+VISCOSE TUBE
300259	ESCOBILLON MAD.+VISCOSA TUBO	SWAB IN TUBE WOOD+VISCOSE
300261	ESCOBILLON PS+ALGODON TUBO	SWAB IN TUBE PP+COTTON
300263	ESCOBILLÓN 13X165MM PS C/POLIÉSTER	SWAB 13X165MM PS W/POLYESTER
300280	CARY BLAIR MADERA+ALGODON	CARY BLAIR SWAB WOOD+COTTON
300281	AMIES ALUMINIO+VISCOSA	AMIES SWAB ALUMINIUM+VISCOSE
300284	AMIES LIQUIDO PS+VISCOSA	AMIES SWAB LIQUID PS+VISCOSE
300285	AMIES CARBON PS+VISCOSA	AMIES+CHARCOAL SWAB PS+VISCOSE
300287	AMIES PS+VISCOSA	AMIES SWAB PS+VISCOSE
300290	STUART MADERA+ALGODÓN	STUART SWAB WOOD+COTTON
300291	STUART ALUMINIO+ALGODÓN	STUART SWAB ALUM+COTTON
300292	STUART ALUMIN.TRENZADO+VISCOSA	STUART SWAB TWISTED ALU + VISC
300294	VIRUS ALUMINIO + POLIESTER	VIRUS SWAB ALUMINIUM POLYESTER
300295	STUART 13X165MM PS C/VISCOSA	STUART 13X165MM PS W/VISCOSE
300296	H. VIRUS ALUM. ALGODÓN	SWAB FOR VIRUS WIRE+COTTON TIP
300297	VIRUS PS+POLIESTER	VIRUS SWAB PS POLYESTER
300299	CHLAMYDIA PS+POLIESTER	CHLAMYDIA SWAB PS+POLYESTER
310200	ESCOBILLON MAD.+ALGODON FLOW	WOOD+COTTON SWAB FLOW
310202	ESCOBILLON PS+VISCOSA FLOW	PS+VISCOSE SWAB FLOW

REF	DESCRIPCIÓN	DESCRIPTION
300211.1	ESCOBILLÓN PS+ALG. PACK PEEL/2	SWAB B/2 PS+COTTON PEEL/2
300212.1	ESCOBILLON PS+VISCOSA PEEL/2	SWAB PEEL/2 PS+VISCOSE
300250.1	ESCOBILLON MAD.+ALGOD. PURO TU	SWAB IN TUBE WOOD+PURE COTTON
300250.M	ESCOBILLON MAD.+ALGODON TUBO	SWAB IN TUBE WOOD+COTTON
300261.M	ESCOBILLON PS+ALGODON TUBO	SWAB IN TUBE PS+COTTON
300268.B	ESCOBILLON PS+POLIESTER PEEL PACK	SWAB PS+POLIESTER IND.WRAPPED
300280.2	CARY BLAIR PS+VISCOSA	CARY BLAIR SWAB PS+VISCOSE
300281/1	ESC. AMIES+CARBON ALUM.VISCOSA	AMIES CHARCOAL SWAB WIRE+VISCOSE
300281T	AMIES ALUMINIO TRENZADO+ VISCOS	AMIES SWAB TWIST WIRE+VISCOSE
300281TC	AMIES+CARBON ALU.TRENZADO+ VISC	AMIES+CHARCOAL TWIS.WIRE+VISCO
300285.M	AMIES CARBON PS VISCOSA 6x100	AMIES CHARCOAL PS RAYON 6X100
300287.5	AMIES PS VISCOSA CAJAS 6x100	AMIES PS VISCOSE CASES 6X100
300287.A	ESCOB.AMIES PS+VISCOSA	AMIES SWAB PS+VISCOSE
300295C	STUART CARBÓN PS + VISCOSA	STUART+CHARCOAL SWAB PS+VISCOS
310253.1	ESCOB. ALUM+VISCOSA FLOW	ALUM+VISCOSE SWAB FLOW
310211.1	ESCOBILLON PS+ALGODON B/2 FLOW	PS+COTTON SWAB B/2 FLOW
300250.MY	ESCOBILLON MAD.+ALGODON TUBO	SWAB IN TUBE WOOD+COTTON
300211.10	ESCOBILLÓN PS+ALG. PACK PEEL/10	SWAB PS+COTTON PEEL/10
300261AV	ESCOBILLON PS+ALGODON TUBO	SWAB IN TUBE PS+COTTON

CE ATITIKTIES DEKLARACIJA

PRODUKTO GAMINTOJAS DELTALAB S.L.

ADRESAS Plaza de la Verneda, 1
Pol. Ind. La Liana
08191 RUBI (BARCELONA) – ISPANIJA

DEKLARUOJAME SAVO ATSAKOMYBE, KAD PRODUKTAS

Pavadinimas INVAZINIAI STERILŪS EUROTUBO SURINKIMO
TAMPONĖLIAI, SKIRTI MĖGINIŲ PAĖMIMUI SU
ARBA BĖ TRANSPORTAVIMO TERPĖS

Tipas Invazinė sterili surinkimo sistema, skirta tiesioginiam
kontaktui su pacientu

Paskirtis Surinkti ir transportuoti biologinius mėginius vėlesnei
mikrobiologinei analizei

GMDN kodas 33722

ATITINKA STANDARTŲ IR DIREKTYVŲ REIKALAVIMUS:

Tamponėlis

Direktyva 93/42/ECC Medicinos prietaisų direktyva. Perkėlimas į Ispanijos teisės aktus Real Decreto 1591/2009.

Klasifikacija: Klasė IIa

KITA INFORMACIJA:

Ši atitikties deklaracija yra paremta CE sertifikato numeriu 2005 06 0474 CP, Produkcijos kokybė užtikrinama pagal Direktyvos 93/42/EEC Priedų V ir VII reikalavimus, išduota Agencia Espanola de Medicamentos y Productos Sanitarios (AEMPS), Notifikuotos įstaigos numeris 0318.

Mėgintuvėlis su transportavimo terpe

Direktyva 98/79/EC In vitro diagnostikos medicinos prietaisų direktyva. Perkėlimas į Ispanijos teisės aktus Real Decreto 1662/2000.

DATA: 2016 m. gegužės mėn. 20 d.

Vardas: .

Parašas:

Pareigos:



EC-Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

Heinz Herenz Medizinalbedarf GmbH
Rudorffweg 10
21031 Hamburg
Germany

With its facility as per attachment 1

has introduced, applies and maintains a Quality Assurance System for the aspects of manufacture **concerned with securing and maintaining sterile conditions** for the products / product categories:

- **Bacterial sample collecting sets**
- **Tongue depressors**
- **Surgical covers**
- **Cotton swabs**
- **Urine bags**

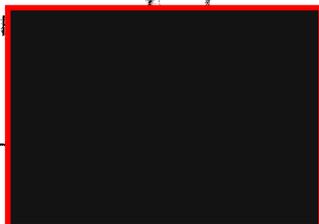
The compliance of the Quality Assurance System with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

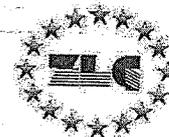
The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 27 April 2024

Report No.: 1249FS22F
Process No.: GS – 1249
Certificate No.: 1249GB415190513



MEDCERT Identification No.: 0482



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

**Attachment 1
EC-Certificate of Conformity
QS - 1249**

This Attachment is valid only in connection with certificate No.: 1249GB415190513

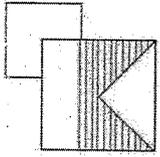
**Heinz Herenz Medizinalbedarf GmbH
Osterrade 54
21031 Hamburg
Germany**

Hamburg, 13 May 2019



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de

ZLG-BS-237.10.15



kaltek

CE ATITIKTIES DEKLARACIJA

KALTEK S.r.l., kurios pagrindinė buveinė yra adresu Via del Progresso No. 2 – 35127 Padova (Italija), visa savo atsakomybe atsakingai pareiškia, kad medicinos produktas, pavadinimu:

STERILUS ŠEPETĖLIS KITO-BRUSH

Prekės kodas 0640

Produktas priskiriamas I sterilių produktų klasei Nr. 5 pagal Direktyvos 93/42/EEB IX skirsnį (pagal pakeitimus išvardintus Direktyvoje 2007/47/EB), kuri galioja Italijoje pagal Dekretą No.46, išleistą 1997 vasario m. 24 d.(ir jo pakeitimus pagal dekretą Nr. 37/10).

Produktas visiškai atitinka reikalavimus pagal Direktyvą 93/42/EB, kaip aprašyta Techniniame faile Nr.FT001KT (kuris laikomas Kaltek pagrindiniame ofise);

Ir yra gaminami pagal aukščiau minėtos Direktyvos kokybės sistemos, kuri atitinka Priedo V reikalavimus, kurie išdėstyti Serifikate Nr. MED24016 išduotame 2004 m. rugpjūčio 26 d. KIWA CERMET S.p.a. notifikuojančios organizacijos, kurios registracijos Nr. 0476. Organizacijos adresas: Via Cadriano, 23 Cadriano di Granarolo (BO).

Padova, 2020 01 07



Kaltek srl - 35127 PADOVA - Italy - Via del Progresso, 2 Z.I. - www.kaltek.it
Tel. +39 049 8703410 r.d. - Fax +39 049 8703383 - E-mail: info@kaltek.it - PEC: kaltek@legalmail.it
Iscritta Registro Imprese di Padova C.F. e n. Iscritz. 02405040284 - R.E.A. di Padova n. 227519
RIVA 02405040284 - Capitale Sociale Euro 100.000,00 I.v. - Registro A.E.E. n. 00802000002192

Il vostro partner ospedaliero
Your best hospital partner

**DICHIARAZIONE DI CONFORMITÀ
DECLARATION OF CONFORMITY
n. 3/DM**

La società KALTEK S.r.l. con sede legale e operativa in Via del Progresso n° 2 – 35127 Padova (Italia), dichiara sotto la propria totale responsabilità che il dispositivo medico denominato:

KITO-BRUSH STERILE - COD. 0640

classe di rischio I[^] sterile, in accordo alla regola 5 dell'allegato IX della Direttiva 93/42/CEE e ss.mm.ii. (emendata dalla Direttiva 2007/47/CE,) recepita in Italia con Decreto Legislativo 24 febbraio 1997 n. 46 e ss.mm.ii. (emendato dal D.Lgs. n. 37/10),

- è conforme ai requisiti essenziali ed alle disposizioni della direttiva 93/42/CEE e ss.mm.ii. come da fascicolo tecnico n. FT001KT (archiviato presso la Kaltek);
- è fabbricato in accordo al Sistema Qualità che soddisfa i requisiti di cui all'Allegato V del sopracitato decreto legislativo, come da Certificato n. MED 24016 rilasciato in data 26/08/2004 da KIWA CERMET ITALIA S.p.A. - Organismo Notificato n. 0476 - Via Cadriano, 23 Cadriano di Granarolo (BO).

KALTEK S.r.l. with operating and legal head office in Via del Progresso No. 2 – 35127 Padova (Italy) certifies, on its own responsibility, that the medical device named:

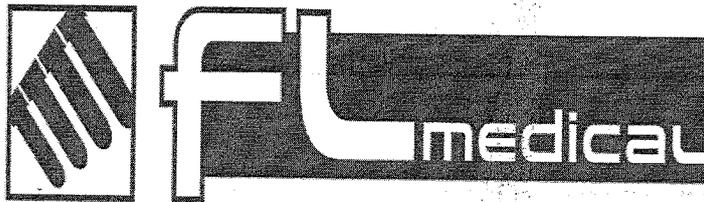
STERILE KITO-BRUSH - REF 0640

risk class I sterile - rule No. 5 - Annex IX of the 93/42/ECC Directive and its following amendments and integrations (emended by the 2007/47/EC Directive) enforced by the Italian decree law No. 46 of 24/02/97 and its following amendments and integrations (emended by decree law No. 37/10)

- complies with the requirements set out in 93/42/ECC Directive and its amendments as described in the Technical File No. FT001KT (archived in Kaltek head office);
- is manufactured according a quality system which complies with the requirements of the Annex V of the above mentioned decree law as per Certificate No. MED 24016 issued on 26/08/2004 by KIWA CERMET ITALIA S.p.A. - notified Body No. 0476 - Via Cadriano, 23 Cadriano di Granarolo (BO).

Padova 07/01/2016





F.L. MEDICAL s.r.l. Unipersonale
Via Enrico Mattei, 20 – 35038 TORREGLIA (Padova) – Italy
Tel. +39 049 5211475 / +39 049 5212835 - Fax +39 049 5212566
e-mail: info@flmedical.com - web site: www.flmedical.com
C.F. e P.IVA 01134840287 - Cap Soc. 90.000 € i.v.
Reg. Imp. di Padova n. 21695 - R.E.A. di Padova n. 187254

ATITIKTIES DEKLARACIJA

F.L. MEDICAL s.r.l. Unipersonale
Turinti būstines
Via Enrico Mattei, 20
35038 TORREGLIA (PADOVA)
ITALIJA

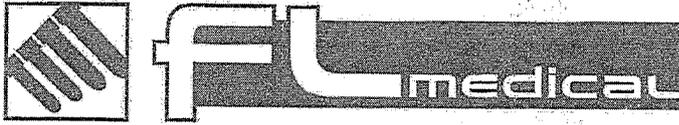
Vienkartinių plastikinių gaminių, skirtų laboratorijos analizei gamintojas, deklaruoja savo atsakomybe, kad toliau nurodyti IVD atitinka esminius reikalavimus pagal direktyvos 98/79/EEC 3priedo, 9 straipsnį:

Biologinių skysčių konteineriai
Sterilūs konteineriai biologiniams skysčiams
Petri lėkštelės, inokuliacinės kilpelės
Mėginių indeliai ir kiuvetės, skirti automatiniams analizatoriams
Pipetėčių antgaliai
Pastero pipetės
Sterilios Pastero pipetės
ESR sistemos
Mėgintuvėliai biologinių skysčių surinkimui
Sterilūs mėgintuvėliai biologinių skysčių surinkimui
Mėgintuvėliai kraujo surinkimui
Vakuuminiai mėgintuvėliai kraujo surinkimui, sterilūs

Techninė dokumentacija saugoma įmonėje, už kurią atsakingas kokybės užtikrinimo vadybininkas

Torreglia, 2020 01 10

F.L. M



F.L. MEDICAL s.r.l. Unipersonale
Via Enrico Mattei, 20 – 35038 TORREGLIA (Padova) – Italy
Tel. +39 049 5211475 / +39 049 5212835 - Fax +39 049 5212566
e-mail: info@flmedical.com - web site: www.flmedical.com
C.F. e P.IVA 01134840287 - Cap Soc. 90.000 € i.v.
Reg. Imp. di Padova n. 21695 - R.E.A. di Padova n. 187254

DECLARATION OF CONFORMITY

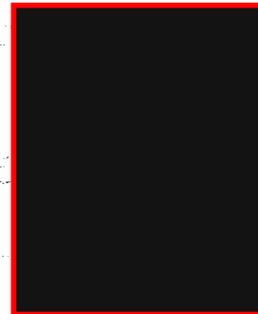
F.L. MEDICAL s.r.l. Unipersonale
Having headquarters in
Via Enrico Mattei, 20
35038 TORREGLIA (PADOVA)
ITALY

manufacturer of disposable plastic wares for analysis laboratory, declares on its responsibility that the IVD below indicated meet the essential requirements of annex 3 according to art. 9 of Directive 98/79/EEC:

Containers for biological liquids
Sterile containers for biological liquids
Petri dishes, spreaders and inoculation loops
Sample cups and cuvettes for autoanalyzer
Tips for pipettes
Pasteur pipettes
Sterile Pasteur pipettes
ESR systems
Test tubes for biological liquids collection
Sterile test tubes for biological liquids collection
Test tubes for blood collection
Vacuum test tubes for blood collection sterile

The technical documentation is located in our facilities under the responsibility of the quality assurance manager.

Torreglia, 10.01.2020



CE ATITIKTIES DEKLARACIJA

Norime pareikšti, kad produktai minimi šiame dokumente atitinka reikalavimus ir visas Tarybos direktyvas, kurie nurodyti žemiau ir yra pagaminti ir išleisti pagal QM-System, galiojančią nuo šios deklaracijos išdavimo datos.

Gamintojo pavadinimas ir adresas:

SARSTEDT AG & Co
Sarstedt str. 1, 51588 Nümbrecht

Anksčiau paminėtas gamintojas yra išimtinai atsakingas už šios atitikties deklaracijos išdavimą.

Ši notifikuoti įstaiga dalyvavo atitikties vertinime:

ne:

Notifikuotos įstaigos pavadinimas:

Produkto pavadinimas:

Šlapimo monovetės/priedai, Šlapimo monovečių rinkiniai

Produkto numeris arba produkto grupė:

Gaminio grupės numeris 10 ir 51

Klasė:

Kita

Taikomos direktyvos:

98/79/EC, priedas III

CE žymėjimas:

CE

Vieta:

Rommelsdorf

Data:

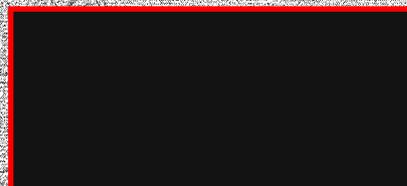
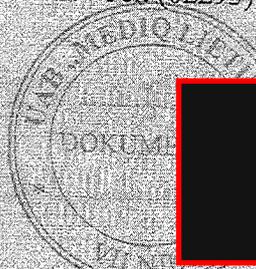
2011 03 28

Parašas: MD Saugos atstovas

QM atsovas

 **SARSTEDT**

SARSTEDT AG & Co. Sarstedt str. 1 51588 Nümbrecht Tel. (02293) 305-0 Faks. (02293) 305-122
Blatt 3(3)/ZQS 03.0-018D



EG-Konformitätserklärung EC Declaration of Conformity

Hiermit erklären wir, dass die hier genannten Produkte die relevanten Anforderungen aller untenstehend genannten Richtlinien erfüllen und gemäß dem zum Zeitpunkt der Ausstellung gültigen QM-System hergestellt und freigegeben sind.

We herewith declare that the products mentioned in this document correspond to the relevant requirements of all Council Directives mentioned below and are manufactured and released according to the provisions of the QM-System in force on the date of issue of this Declaration.

Name und Adresse des Herstellers: SARSTEDT AG & Co.
Name and address of manufacturer: Sarstedtstr. 1, 51588 Nümbrecht

Der oben genannte Hersteller trägt die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung.

The above mentioned manufacturer is exclusively responsible for the issuance of this Declaration of Conformity.

Die folgende benannte Stelle war an der Konformitätsbewertung beteiligt: keine:
The following notified body was involved in the evaluation of conformity: none:

Name:
Name:

Produktname: Urin-Monovetten/Zubehör, Urin-Monovetten Sets
Product name: Urine-Monovettes/accessories, Urine-Monovette® Sets

Artikel-Nr. bzw. Artikel-Gruppe: Warengruppe 10 und 51
Product number or product group: Article group number 10 and 51

Klasse/class: sonstige/other

Angewandte Richtlinien: 98/79/EG, Anhang III
Applied Directives: 98/79/EC, annex III

CE-Zeichen, CE-mark: 

Ort:
Place:

Unterschrift:
Signature:

 **SARSTEDT**