

## SWABS FOR MICROBIOLOGICAL SAMPLING

- Swabs are used for biological sampling.
- Specially used for processing samples which, after being coloured, will be analysed by microscopy.
- Also suitable for isolations in culture medium.
- Another important use is its capacity to spread dishes by dissemination techniques (for example for susceptibility testing by Kirby-Bauer or by E-test).

## SWABS

The swabs intended for the collection and transport of microbiological samples are considered invasive medical devices for temporary use. As such, they comply with the safety and performance requirements determined by EU Regulation 2017/745 (which will replace Directive 93/42 / EEC on medical devices in May 2020).

According to the rules of classification of this Regulation these swabs belong to class IIa since they are of surgical use.

The **Agencia Española del Medicamento y Productos Sanitarios** (AEMPS – ON 0318) is the institution who certifies these swabs.

## QUALITY STANDARDS – REQUIREMENTS FULFILLED BY SWABS

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| <ol style="list-style-type: none"> <li>1. UNE-EN ISO 556-1 Sanitary products sterilisation. Requirements to be designed as “STERILE”. Part 1: sterilised sanitary products requirements. Requirements for medical devices in their terminal state.</li> <li>2. UNE-EN ISO 868-2 Packaging materials for medical devices sterilized in its final phase. Part 2: sterilization wrap. Requirements and test methods.</li> <li>3.* UNE-EN ISO 11737-1 Sterilization of medical devices. Microbiological methods. Part 1: determination of a population of microorganisms.</li> <li>4.* UNE-EN ISO 11737-2 Sterilization of medical devices. Microbiological methods. Part 2: Sterility tests performed for the definition, validation and maintenance of a sterilization process.</li> <li>5.* UNE-EN ISO 11135-1 Sterilization of medical devices. Ethylene oxide. Part 1: requirements for development, validation and control of the routine of a sterilization process of medical devices.</li> </ol> | <ol style="list-style-type: none"> <li>6.* UNE-EN ISO 11137-1 Sterilization of health care products. Radiation. Part 1: requirements for the development, validation, and control of the routine of a sterilization process of PS.</li> <li>7.* UNE-EN ISO 11137-2 Sterilization of health care products. Radiation. Part 2: setting the sterilization dose.</li> <li>8. UNE-EN ISO 15223-1 Sanitary products. Symbols to use on labels, labelling and information to be supplied. Part 1: general requirements.</li> <li>9. UNE-EN ISO 14971 Sanitary products. Application of risk on management.</li> <li>10. UNE-EN ISO 13485 Sanitary products. Systems of quality management. Requirements for regulatory purposes.</li> </ol> |
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\* These rules apply to sterile swabs.



## SWABS USE ACCORDING TO THE MATERIAL

### SWAB HEADS

Are made of various materials, including cotton, polyester and viscose. Each swab contains more or less 0.04g of fiber and its absorption capacity is 0.2-0.3ml, with cotton usually having a better absorption of liquid, although the difference is minimal.

#### Cotton/Pure Cotton:

Fibrous substance, white and soft. Being a vegetable fiber can include traces of some substance (fatty acids, oils, etc.) that affect labile or demanding microorganisms.

#### Polyester (Dacron):

For use in direct antigen, PCR, IFA tests. Its drawback is that it contains fatty acids and inhibitory detergents. It has flame retardant properties.

#### Viscose (Rayon):

Artificial silk obtained from cellulose. It is a more aseptic material and the one with less effects inhibitory has in bacterial growth. Therefore, it is the best material for cell recovery.

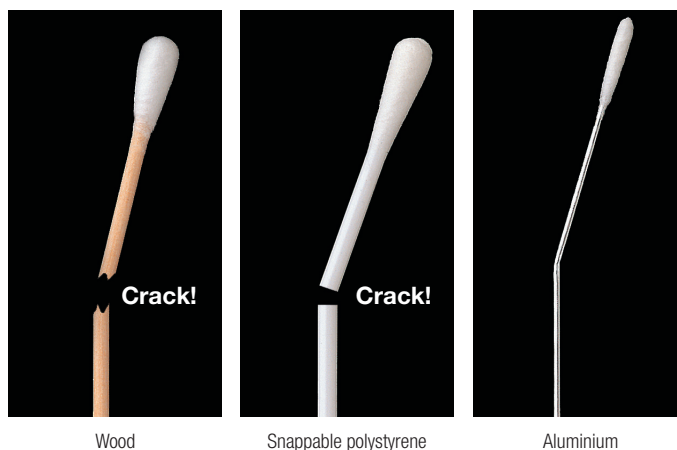
#### Flocked polyester:

Material with high absorbency and overall sample elution.



### SWABS SHAFT

The shaft is available in different materials according to its application: In wood, in polystyrene (breakable without leaving splinters) and also in aluminium.



Wood

Snappable polystyrene

Aluminium

## PRESENTATIONS



**In bulk:**  
the non-sterile swabs presented in bags of 100 units.



**Peel-pack package:**  
Plastic unit bag - plastic or medical paper - plastic (according to reference).



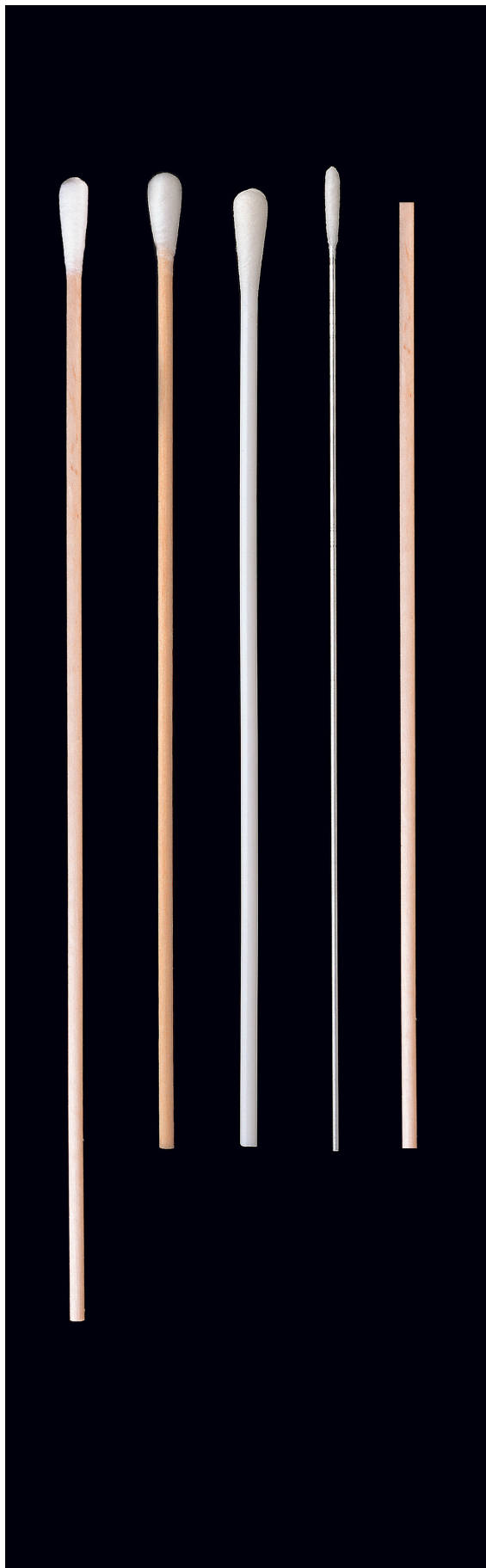
**Flow-pack package:**  
single bag. Polypropylene bioriented bag.



**Package in polypropylene tube:**  
On the label that acts as a seal, the product is identified.

All sort of package have the following parameters printed on: product code, product description, lot number, expiry date, CE mark, manufacturer name and address, sterilisation method and single use mark (Ⓜ).

## TRADICIONAL SWABS WITHOUT TRANSPORT MEDIUM



### Non sterile swabs

Model **300232** is longer than the traditional swabs and is designed for those hard to reach places.

For use in **gynaecology** when taking endocervical cells while using the speculum.

#### Dimensions:

**300232** shaft 200 x 2.5 mm. Tip 5 mm Ø.

**300205** shaft 147 mm ± 0.3 mm x 2.2 mm ± 0.3 mm Ø.

#### Other models dimensions:

Wood: shaft 150 x 2.2 mm (tip Ø ± 5 mm).

Polystyrene: shaft 150 x 2.5 mm (tip Ø ± 5 mm).

Aluminium: shaft 147 x 0.9 mm (tip Ø ± 1.5 mm).

They are supplied in bags of 100 units, excepting code **300205**, supplied bulk.



code	shaft material	tip material	case quantity	case weight	case volume
<b>300232</b>	extra large wood (200 mm)	cotton	80 x 100	5.0	0.032
<b>300230</b>	standard wood (150 mm)	cotton	100 x 100	4.65	0.032
<b>300260</b>	polypropylene	cotton	40 x 100	2.5	0.012
<b>300260.1</b>	polystyrene	viscose	40 x 100	2.5	0.014
<b>300243</b>	aluminium	cotton	100 x 100	2.8	0.005
<b>300205*</b>	wooden shaft only	-	1 x 1,000	2.5	0.010

\* Non CE product.

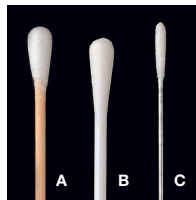
Expiry date: 60 months

### Sterile swabs

Sterile swabs individually wrapped in peel-pack or flow pack, depending on the model. **Sterilized.**

For use when samples do not need to be transported.

It is recommended our transport swabs in tubes when sample transport is required (see next page).



A: Wood  
B: Snappable polystyrene  
C: Aluminium

code	shaft material	tip material	sterile	package	case quantity	case weight	case volume
300200	wood	cotton	STERILE R	peel-pack	2 x 1,000	2.25	0.029
310200	wood	cotton	STERILE R	flow-pack	2 x 1,000	2.60	0.029
300201	snappable PS	cotton	STERILE R	peel-pack	2 x 1,000	3.52	0.027
300202	snappable PS	viscose	STERILE R	peel-pack	2 x 1,000	3.50	0.029
310202	snappable PS	viscose	STERILE R	flow-pack	2 x 1,000	2.02	0.029
300203	aluminium	cotton	STERILE EO	peel-pack	2 x 1,000	2.40	0.029

Cases per pallet: 54.

Expiry date: 48 month from sterilization date.

1. Flow-pack
2. Peel-pack



### Sterile swabs (2 units)

Two Sterile swabs wrapped in peel-pack, depending on the model. **Sterilized by ethylene oxide.**

One swab is designed for cleaning the sampling area.

The other swab is designed for sample collection.

For use when samples do not need to be transported.

It is recommended our transport swabs in tubes when sample transport is required 1,000 peel-packs with 2 units each one per case.

code	shaft material	tip material	sterile	package	case quantity	case weight	case volume
300210	wood	cotton	STERILE EO	peel-pack	1.000	2.65	0.024
300212.1	snappable PS	viscose	STERILE EO	peel-pack	1.000 peels	2.72	0.025



Cases per pallet: 54.

Expiry date: 48 month from sterilization date.

### Medical paper+ plastic





### Sterile swab in round tube

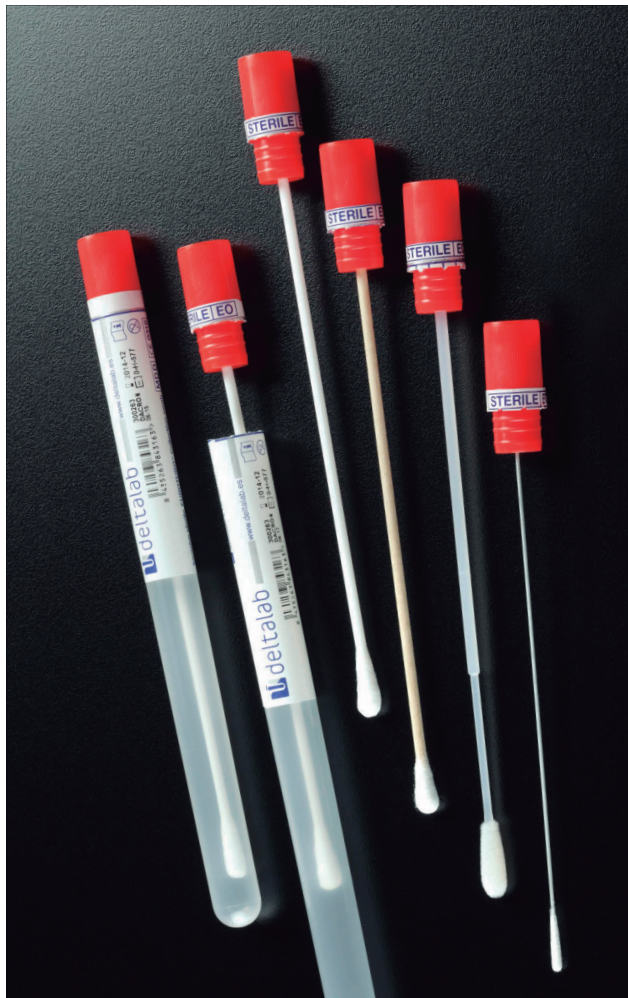
Sterile dry swabs supplied in shockproof round bottom polypropylene tube, with a label sealing the cap.  
 Dimensions of tube: Ø 13 x 165 mm.  
**Sterilised by ethylene oxide.**

code	shaft material	tip material	case quantity	case weight	case volume	cases per pallet
300250	wood	cotton	4 x 500	14.00	0.060	24
300250.1	wood	pure cotton	4 x 500	14.00	0.070	24
300261	snappable PS	cotton	4 x 500	14.90	0.070	24
300252	snappable PS	viscose	4 x 500	15.00	0.066	24
300263	snappable PS	poliéster	4 x 500	15.00	0.062	24
300251	aluminium	cotton	4 x 500	15.00	0.066	24
300253	aluminium	viscose	4 x 500	13.90	0.070	24
300265*	PS	flocked polyester	4 x 500	14.20	0.065	24

Expiry date: 48 month from sterilization date.  
 \*Code not available for sale in Italy, UK and Ireland. Class I Sterile product"



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



### Human DNAsa, RNAsa and DNA free certified swabs, steriles

Human DNA free Certified. **Sterilised by ethylene oxide.**  
 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	shaft material	tip material	selling unit	case quantity	case weight	case volume
300252DNA	polystyrene	viscose	500	4 x 500	14.20	0.070

Expiry date: 48 months from sterilisation date



This product is not considered a medical device and does not carry CE marking because it is not for a subsequent diagnosis of a pathology, but is designed for saliva sampling, for genetic analysis (identification of human DNA) within the scope of the investigation and the forensic market.

