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Capitale Sociale € 309.600,00
R.E.A. MI 882798
Reg. Imp. C.F. e P.I. MI 01794050151

PRODUCT DATA SHEET
SWABS

Description
Swabs, sterile or non-sterile.

Intended use and mark
Devices for taking samples from natural orifices in the human body.

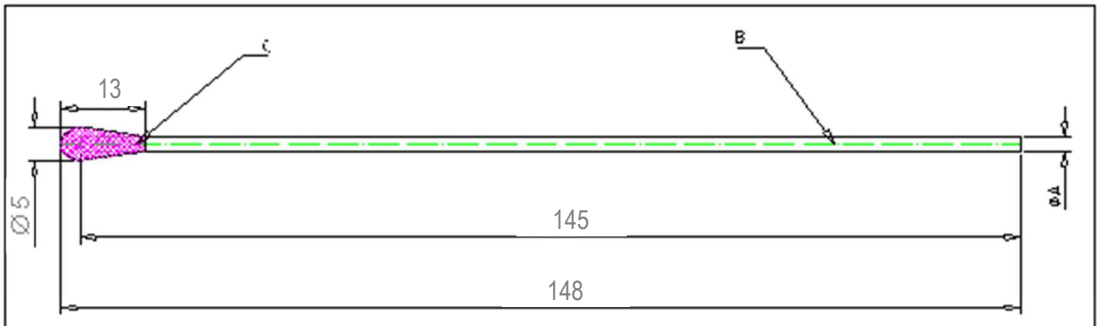
All LP Swabs non-sterile have the CE conformity marking as Medical Device, according with 745/17 UE Regulation.

LP sterile Swabs have the CE conformity marking together with the identification code of the Notified Body which periodically monitors the conformity of the product, obtained according to the procedure of annexes V and VII of Directive 93/42 / EEC (see Table A).

Indications of use
Swabs are means for manually collecting samples of bacterial flora from the human body.
This is possible thanks to the characteristics of the tip (cotton or Rayon) which facilitate collection without damaging the material.
Swabs do not operate autonomously, but require a professional operator in charge of the collection. They are simple and intuitive to use.
The collection usually takes place by means of a simple "smear" of the tip of the swab against the intact internal tissues of a patient's natural orifice, such as: nose and pharynx, eye, ear, respiratory system, vagina, rectum.
Swabs are disposable; the contact time with the patient is short (not more than one minute) and is intended to be used by professional operators on patients of any age.

Material
Manufactured in two different materials, cotton and Rayon. They may also have a plastic, wood or wire stick.

Technical Features (dimensions in mm.)



DIM "A"	MATERIAL "B"	MATERIAL "C"
Ø 2.2	WOOD	COTTON
Ø 2.2	PLASTIC	COTTON
Ø 0.9	ALUMINIUM	COTTON
Ø 2.5	PLASTIC	RAYON
Ø 2.2	PLASTIC	RAYON-VISCOSE

Chemical-Physical Features

Swab head

Material	Cotton or Rayon (Viscose), according to European Pharmacopeia
Nominal haed, diameter	mm. 6,00
Maximum humidity	≤ 8 %
Resistance to detaching from stick	>20 N

Stick

Wood: maximum humidity	Maximum humidity < 14 %
Plastic, material	PS HI – polistirene high Impact
Metal, material	Aluminium

Table A: component parts

			DESCRIPTION					
						Packaging[1]		
							Individual	
Code	Mark	Registration number NDMD[7]	Head[5]	Stick[5]	Sterile[6]	Multiple[2]	Single[3]	Double[4]
112191	CE	48222/R	Cotton	Wood	no	30 x 100 pcs	---	---
112298	CE0051	48143/R	Cotton	Wood	yes	---	Blister	---
112491	CE	48226/R	Cotton	Plastic	no	30 x 100 pcs	---	---
112498	CE0051	47314/R	Cotton	Plastic	yes	---	Blister	---
112591	CE	48227/R	Rayon	Plastic	no	30 x 100 pcs	---	---
112598	CE0051	48158/R	Rayon	Plastic	yes	---	Blister	---
112691	CE	48228/R	Cotton	Metal	no	30 x 100 pcs	---	---
112698	CE0051	48164/R	Cotton	Metal	yes	---	Blister	---
111198	CE0051	43769/R	Cotton	Plastic	yes	8 x 100 pcs	PS tube, labelled	---
111298	CE0051	47311/R	Cotton	Plastic	yes	---	PS tube, labelled	easy peel Blister

Note:

1. Packaging: In addition to the outer box
2. LDPE sealed bags x pieces
3. Individual single: Materials resistant to ionizing radiation
   Blister: PA/PE (30/70) film and medical paper, 4 welded edges
   Tube: In PS ø16x150 mm used as container, labelled; swab assembled with its stopper.
4. Individual double: Swab in a tube, packed in blister.
5. See chemical-physical specifications, page 2
6. Sterility: Where applicable swabs are irradiated to a SAL (Sterility Assurance Level) of 10^{-6}, if package is unopened and undamaged.
7. Cultiplast swabs are MDD products registered with the National Directory of Medical Devices (NDMD).

Environmental information

LP swabs are disposable: once used, they must be disposed according to the instructions given at the locations where they are used.

All dimensions indicated are nominal. Technical specifications are subject to change without prior notice.