



TECHNICAL SHEET T0686ST

STERILE SWAB

MANUFATURER : KALTEK srl
CLASSIFICATION : Class I sterile – Temporary invasive – rule 5
EMDN : M010103
GMDN : 33721

NOTIFIED BODY : n. 0476 KIWA CERMET ITALIA spa
Via Cadriano 23 40057 Cadriano di Granarolo Emilia (BO)

INTENDED USE : SWAB FOR SAMPLING

PRODUCT AVAILABILITY

| REF | ROD | TIP | PRIMARY PACKAGING | PACKAGE FOR SALE |
|------|---------------|--------|-------------------|------------------|
| 0686 | Wood | Cotton | Single | 1000 pcs |
| 2873 | Wood | Cotton | 2 pcs | 2000 pcs |
| 2875 | Wood | Cotton | 10 pcs | 5000 pcs |
| 3208 | Polypropylene | Rayon | Single | 1000 pcs |



FEATURES

Sterile disposable swab for cell sampling and/or absorption of exudates from small wounds; available with wooden and plastic rod. Cotton and viscose (rayon) fibres are in compliance with the requirements of International Pharmacopoeia and do not contain any inhibitory substance and fluorescent brightening agent. Packaging is made in medical paper/transparent PE; product and packaging raw materials are phthalate **and latex free**.

| TYPE | TOTAL LENGHT | TIP LENGHT | ROD LENGHT | Ø TIP | Ø ROD | WATER ABSORBENCY |
|-------------|--------------|-------------|--------------|--------------|---------------|------------------|
| WOODEN SWAB | 150,0 ± 4 mm | 15,0 ± 4 mm | 148,0 ± 2 mm | 5,0 ± 1,5 mm | 2,2 ± 0,15 mm | ≥ 0,15 g/pc |
| PP SWAB | 150,0 ± 4 mm | 15,0 ± 4 mm | 148,0 ± 2 mm | 5,0 ± 1,5 mm | 2,5 ± 0,15 mm | ≥ 0,15 g/pc |

STERILIZATION : Ethylene Oxide

PRODUCT EXPIRY : 5 years provided it is properly stored and undamaged

CAUTION

For use only under trained medical staff. Disposable, do not reuse.
Use only if the package is undamaged. Use immediately after opening.

STORAGE AND DISPOSAL

Keep in cold and dry place out from heat sources.
It is recommended to move cartons using means and protections to prevent damages and/or deterioration of packages.
Disposed of the medical device in accordance with local authorities. Incineration does not produce toxic residues.

CONFORMITY

93/42/EEC (with special reference to Dir. 2007/47/EC)
UNI CEI EN ISO 13485
UNI CEI EN ISO 14971
UNI CEI EN 1041
UNI CEI EN ISO 15223-1
UNI EN ISO 10993-1-5
UNI EN ISO 11135-1
UNI EN 556-1
UNI EN ISO 14644-1
UNI EN 11737-1