

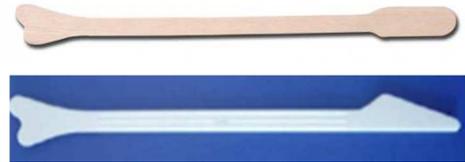
# TECHNICAL SHEET S0877ST

## STERILE AYRE SCRAPER



MANUFACTURER : KALTEK srl  
CLASSIFICATION : Class I sterile – Temporary invasive - rule 5  
EMDN : U089002  
GMDN : 32679

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



### INTENDED USE

The medical device is intended for cytological samplings of the fornix and esocervix cells for cervix cancer screening procedures (Pap-test).

### MATERIAL

Product raw materials and packaging are phthalate and latex free.

REF	MATERIAL	DIMENSIONS	PACKAGING
0877	Birch wood	175 ± 2% - thickness 1,60 mm	Single pack – medical paper
1014	White ABS	180 ± 2% - thickness 1,60 mm	Single pack – medical paper / transparent PE

**STERILIZATION** : Ethylene Oxide (ETO)

**UNIT FOR SALE** : 500 pcs/box

**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 a 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 the packages.  
Disposed of in accordance with local authorities. Incineration does not produce toxic residues.

### CONFORMITY

93/42/EEC (amended by Dir. 2007/47/EC)  
UNI EN ISO 9001  
UNI EN ISO 13485  
UNI CEI EN ISO 14971  
UNI CEI EN 1041  
UNI CEI EN ISO 15223-1  
UNI EN ISO 10993-1-5-10  
UNI EN ISO 11135-1  
UNI EN 556-1  
UNI EN ISO 11607-1  
UNI EN ISO 14644-1  
MEDDEV 2.7.1 – 2.4/1 – 2.12-1 – 2.12/2 guidelines