

kaltek srl

Via Liguria, 29 - 35020 SAONARA (Pd)
Tel. +39 049 8703410 Fax +39 049 8703383
Codice Fiscale e P. IVA 02405040284

il vostro partner ospedaliero
your best hospital partner

TECHNICAL SHEET

K0640ST

KITO BRUSH STERILE



MANUFACTURER : KALTEK srl
CLASSIFICATION : Class I sterile – Temporary invasive - rule 5
EMDN : U09030301
GMDN : 35442
NOTIFIED BODY : n. 0476 KIWA CERMET ITALIA spa - Via Cadriano 23 - 40057 Cadriano di Granarolo Emilia (BO)

REF	PACKAGING	UNIT FOR SALE
0640	Single package – medical paper / transparent PE	500 pcs/box



INTENDED USE

Sterile brush for endocervical sampling used in gynecology for cervix cancer screening procedures (Pap-test).

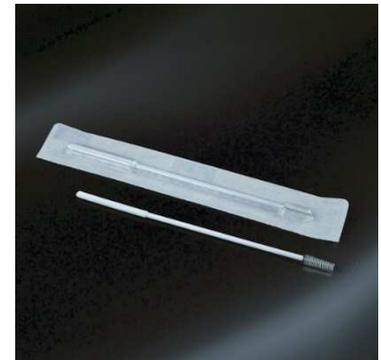
MATERIAL

Product and packaging raw materials are not toxic, phthalate free and latex free.

Stick: High density polyethylene

Brush: Nylon (not traumatic synthetic hypoallergenic bristle) – metallic

Wire: stainless steel



DIMENSIONS	total length	190 ± 2% mm
	brush	21 ± 2% mm
	∅ handle	3 mm
	∅ conical brush	from 6 to 8 mm

STERILIZATION : Ethylene Oxide (ETO)

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 packages damages.

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

UNI EN 11737-1