



SELEFA® Cotton tipped applicator

REF: 120783, 120795

SELEFA® Cotton tipped applicators are designed to be used for wound treatment, cleansing of a treated site, application of medication, ointments and liquid substances and variety of other uses. The device is non-sterile and maximum bioburden level is 100 CFU/g.

Key Features

- ▶ Really smooth surface, no spikes risk
- ▶ 100% cotton tips
- ▶ Birchwood material
- ▶ PVC-free and latex-free device
- ▶ 100-pack

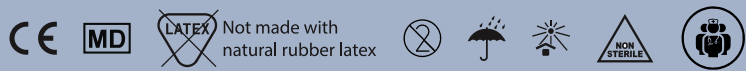


REF	DESCRIPTION	SIZE	Pack Count dispenser/carton
120783	Cotton tipped applicator, single tip, 100-pack, non-sterile	15 cm	100 / 24000
120795	Cotton tipped applicator, double tip, 100-pack, non-sterile	8 cm	100 / 24000

Sales Unit: Transport Carton

Regulations

The product complies with legal requirements for medical devices.



REACH regulation:	The products covered by this data sheet do not contain substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), including any of the Substances of Very High Concern (SVHC) as listed in the latest available version of the Candidate List published by European Chemicals Agency (ECHA).
Biological evaluation:	EN ISO 10993-5 EN ISO 10993-10
Compliance with legal requirements:	Medical Device Regulation (EU) 2017/745, MDR class I
Compliance with product standards:	EN 14079
Quality standards:	EN ISO 13485
Label information and packaging compliance:	EN ISO 15223-1, EN ISO 20417

Material

Product Part	Raw Material & Characteristics
Stick	Wood (Birch)
Head	100% cotton

Warnings & Recommendations

Warnings	The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur.
Storage Recommendation	Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sunlight, other intensive light sources and ozone.
Disposal Recommendation	Dispose in accordance with local regulations.
Shelf Life	5 years

Packing Information

Package	Material	Size (L x W x H) mm
Single Pack	PE bag, Transparent	
Dispenser Pack	Carton, TCF or ECF quality	120783: 180 x 100 x 190 120795: 105 x 95 x 64
Transport Carton	Carton, TCF or ECF quality	120783: 470 x 325 x 400 120795: 435 x 315 x 345
Packing Tape	PVC-free, Transparent	N/A

Barcodes / UDI-DI

REF	Single Pack	Dispenser	Transport Carton
120783	06438129152685	06438129352689	06438129552683
120795	06438129152692	06438129352696	06438129552690

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