

TECHNICAL DATA SHEET

Spike-CRN® STANE

TDS CNSSPKEN

Date: 12.02.2024

Pag. 1/2

DEVICE PARTS INTENDED PURPOSE Microperforator for crn®CRONO® Reservo.

Microperforator for aspiration of drugs to be used with crn®CRONO® Reservoir syringes.

CLASSIFICATION

Class Is medical device, according to Rule 2 of Annex IX of 93/42/EEC European directive and subsequent changes introduced by the 2007/47/EC European directive.

MANUFACTURER

MULTIMEDICAL s.r.l.

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CE MARKING	((0123	
ITALIAN REPERTORY NUMBER OF MEDICAL DEVICES (RDM)	1364422	
ITALIAN CLASSIFICATION OF DEVICE (CND)	A0704	
CANÈ REF	SPIKE/04	
MANUFACTURER REF	091548/1	

PART No.	DESCRIPTION	MATERIAL
1	Microperforator with female Luer Lock connector (ISO 80369-7)	ABS
2	Tip cover	PE
3	3 μm air filter	PP with hydrophobic membrane
4	Male Luer-Lock cap (ISO 80369-7)	ABS

DEVICE SPECIFICATION

Sterile, single-use, non-pyrogenic, non-resterilizable product. Device free of latex and phthalate components (DEHP).



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Pag. 2/2

PACKAGING	GTIN	PCS	FEATURES	MATERIAL
Primary	08050046231373	1	Blister 12x5 cm	Medical degree Paper PP/PE Plastic film
Secondary	18050046231370	60	Bag	PE
Tertiary	28050046231377	300	Box 39x29x20 cm	Corrugated cardboard

ENVIRONMENTAL CONDITIONS FOR STORAGE AND TRANSPORT	EXPIRY DATE
Store the product away from direct exposure to sunlight, in dry and clean environments and away from extreme temperatures and excessive humidity.	4 years and 11 months from the date of manufacture.



WARNINGS

Disposable consumables must be disposed of in accordance with the regulations governing the disposal of medical waste.