PRODUCT DATA SHEET



Tracoe Technical Equipment – REF 730-5

Tracoe Smart Cuff Manager

Product Description

The category Technical Equipment refers to medical devices that allow the pressure in the cuffs of tracheostomy and endotracheal tubes to be set or independently regulated with great precision.

The Tracoe Smart Cuff Manager monitors and regulates the internal pressure of High-Volume Low-Pressure Cuffs) of tracheostomy tubes as well as endotracheal tubes.



Scope of Supply

- Tracoe Smart Cuff Manager
- Tracoe connection tube REF 702

General Information	
Product line	Technical Equiptment
Legal manufacturer	Tracoe Medical GmbH Reichelsheimer Straße, 1/3, 55268 Nieder-Olm Germany
Country of origin	Germany
Handling	STERUZE (11) MR
Shelf life	2 years
Maximum Useful Life	29 days

5 pieces
43 x 80 x 161 mm
312 g
Cardboardbox
Sterile bag with medical paper and transparent heatsealable PET/PP foil

Material Specifications	
Material Housing	Acrylonitrile buta-diene styrene (ABS)
Material Ballon	Termoplastic elastomer (TPE)
Biocompatibility	ISO 10993-5 and 10993-12
XDUT XATE	



Product specifications	
Weight	16 g
Dimensions (L x H)	55 x 77 mm

Storage	
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Certification	
Product classification acc. MDR	lla
CE Marking	((
GMDN	35401
Quality system certified to	EN ISO 13485
FDA registration	Clearance Number K152865



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