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Product Information

Freevent® O2 Adaptors



Product description:

Freevent O2 Adaptors are accessories that fit Freevent XtraCare and Freevent XtraCare Mini. They are clicked over the base of the HME and the combined device is attached to the patient's tracheostomy tube, or similar device. Additional oxygen can then be supplied via the oxygen port of the O2 Adaptor. Freevent O2 Adaptors are single use devices and should be replaced if they become dirty, or at least every 24 hours.



The O2 Adaptor mounted on a Blue Freevent XtraCare

Product Information

Document ID:	PF069-02-TechInfo	Edition:	04
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby,Sweden		
Classification: (EU) 2017/745	Class IIa (1.2 rule 2)		
Intended Use:	Freevent O2 Adaptor and Freevent O2 Adaptor Mini are single use accessories used together with Freevent XtraCare or Freevent XtraCare Mini respectively. The devices are intended to enable additional oxygen supply for patients breathing through a tracheostoma during use of Freevent XtraCare and Freevent XtraCare Mini.		
Use specifications:	<p>Intended medical indication Patients breathing through a tracheostoma, long-term and short-term, independent of underlying condition.</p> <p>Intended patient population For patients with any health condition who breathe spontaneously through a tracheostoma and use applicable Freevent product.</p> <p>Intended usage Disposable single use product. Should be changed at least every 24 hours. For prescription only.</p> <p>Intended part of the body/type of tissue applied to or interacted with: To be applied on applicable Freevent XtraCare, which in turn is connected to a tracheostomy tube or similar device.</p> <p>Intended user profile Clinicians, caregivers, patients, depending on the condition of the patient.</p> <p>Intended conditions of use Environment of use: Hospitals, ICU, Sub-acute care institutions, and home, indoors and outdoors. The device itself does not affect the patient's mobility.</p>		
Contraindications:	No known contraindications.		
CE Mark:	Yes. Devices are CE-marked.		
GMDN code:	58705 (Tracheostoma protective filter)		
Sterilization:	Non-Sterile		
Raw material:	Polypropylene (PP)		
Latex information:	Not manufactured with natural rubber latex		
Biological origin:	The device is not manufactured with materials derived from human or animal source.		
Handling and storage:	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.		

Product Information

Waste handling and disposal:	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
Hazardous components:	None
Expiration date:	3 years after manufacturing.
Packaging:	Freevent O2 Adaptors are single packed in a plastic bag of polyethylene and then 10 pieces in a cardboard box together with IFU.

Devices under Basic UDI-DI:

REF	Name	UDI-DI
7769	Freevent O2 Adaptor 10pcs	07331791008986
8007	Freevent O2 Adaptor Mini 10pcs	07331791015311

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Freevent XtraCare White/Blue	7331791-HME-0-000-0004-XM
Freevent XtraCare Mini White/Blue/Pink <i>(for O2 adaptor Mini)</i>	7331791-HME-0-000-0004-XM