Document ID: PF068-07-Tech Info	Edition: 00

REF Number	7756
Product Name	HME DigiTop O2 (REF7756)
Models:	One variant, fitting for 22mm HME Cassette. One product, each containing one DigiTop O2 + Instructions For Use.
Classification: (MDD 93/42/EEC)	Class IIa, 1.2 rule 2
CE Mark:	Yes
GMDN code:	58705
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The HME DigiTop O2 is an accessory to ProTrach HMEs and Provox FreeHands HME's. For patients spontaneously breathing through a tracheostoma and having a need of extra oxygen.
Description:	HME DigiTop O2 is a top that can be occluded with two digits to enable speech. The device shall be attached to either ProTrach HME 15 or HME 22 before use. The oxygen connector port on the device shall be connected to an oxygen supply via a tube
Sterilization:	Non-sterile
Raw material:	HME DigiTop O2: Blue POM .
Latex information	The device is not manufactured with natural rubber latex.
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight. Temperature limit: 2-42 °C.
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:	REF 7756, HME DigiTop O2: – box with 1 pcs plastic jar with 1 pc HME DigiTop O2 + 1 pc IFU REF 10721.

Technical Info / Material Data Sheet

Reviewed by:

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Vice President QA&RA

2014-03-28

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Date

Approved by:

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Vice President Design Control

2014-04-01

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Date