Technical Info / Material Data Sheet

Document ID: PF004-01-TechInfo | Edition: 05

REF Number	7101-7106, 7111-7116
Product Name	Provox® NID™
Models:	2 model diameters; 17 Fr (5.67 mm) and 20 Fr (6.67 mm). 6 model lengths; 6, 8, 10, 12, 14 and 18 mm.
Classification: (MDD 93/42/EEC)	IIb (2.1 Rule 5)
CE Mark:	Yes
GMDN code:	44412 (Tracheoesophageal speech valve, nonindwelling)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The Provox NID voice rehabilitation system is intended for use in prosthetic voice rehabilitation after total laryngectomy only by patients who have been trained in the use of the device and, as assessed by the clinician who prescribes the device, have demonstrated the ability to understand and consistently follow Instructions for Use without clinician supervision. The Provox NID is intended for single patient use.
Description:	Provox NID is a non-indwelling voice prosthesis for patients who are capable of handling the exchange and maintenance of a voice prosthesis independently of a clinician or physician. The prosthesis is available in two outer shaft diameters (17 and 20 French) and several lengths.
Sterilization:	Non-sterile.
Raw material:	Prosthesis: Silicone and Polyvinylidene flouride (PVDF). Medallion with thread: Silicone and polypropylene (PP). Inserter: Polypropylene (PP).
Latex information	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:	5 years after manufacturing.

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Packaging:

Provox NID is packed together with NID Inserter in a blister package made of PETG film and a top film made of spun-bonded polyethylene. It is then packed in a carton box containing the blister package and instructions for use.

Reviewed by:

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Vice President QA&RA

2014-05-20

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Date

Approved by:

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Vice President Design Control

2014-05-20

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Date