

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Sara Dahl - X-SARDAH	2021-11-19 - 18:38
Reviewed:	QA	John Wennborg - JOHWEN	2021-11-22 - 11:42
Approved:	DD	Jon Berg - JONBER	2021-11-22 - 14:31
Released:	QA	Sara Dahl - X-SARDAH	2021-12-10 - 09:52

This document has been electronically signed by the persons above.

Provox® Measure



Product description:

Reusable instrument for measuring the length (corresponding to voice prosthesis size) of TE punctures. The single-use flanges of Provox Measure can be attached to the instrument in two different ways, facilitating measurement of fistulas made for different voice prosthesis diameters.

Product Information

Document ID:	PF010-01-TechInfo	Edition:	11
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
Classification: (EU) 2017/745	Class I, Rule 5		
Intended Use:	The Provox Measure is intended for sizing the length (corresponding to voice prosthesis length) of tracheoesophageal (TE) punctures.		
Use specifications:	<p><i>Intended medical indication:</i> For measuring the length (corresponding to voice prosthesis length) of the tracheoesophageal (TE) punctures in laryngectomized patients.</p> <p><i>Intended patient population:</i> Patients of any age. Cognitive ability, by a clinician judged as sufficient. Manual dexterity, by a clinician judged as sufficient.</p> <p><i>Intended usage:</i> Provox Measure is sterilizable. Provox Measure Flanges are for single use.</p> <p><i>Intended part of the body/type of tissue applied to or interacted with:</i> The device will contact intact skin and mucosal membrane in the tracheoesophageal puncture.</p> <p><i>Intended user profile:</i> The product is supposed to be handled by physicians, trained nurses, SLPs and clinicians.</p> <p><i>Intended conditions of use:</i> Hospital use. Not continuous use.</p>		
Contraindications:	Do not use the device on punctures of diameter less than 20 Fr as this may cause damage and/or bleeding of the puncture. The device is not intended to be used at the time of surgical creation of the puncture.		
CE Mark:	Yes. Devices are CE-marked.		
GMDN code:	62126 (Tracheoesophageal fistula gauge)		
Sterilization:	Non-Sterile, The Provox Measure instrument is sterilizable by steam.		
Raw material:	Rod: Stainless steel Tube: Polyoxymethylene (POM) Flange: Silicone with blue masterbatch		
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.		
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.		



Product Information

Hazardous components: None

Expiration date: 5 years after manufacturing.

Packaging:
7270 Provox Measure:
 The Provox Measure instrument and 6 pieces Provox Measure Flanges are packed separately in plastic bags together with instructions for use (90727) and cleaning/sterilization instructions (10025-1). The bags are packed in a cardboard box.
7271 Provox Measure Flanges:
 The Provox Measure Flanges are packed 5 pieces in a plastic bag together with 1 instructions for use (90727).

Document No: 10000038338 Edition: 11 Release date: 2021-12-10

Released

Product Information

Devices under Basic UDI-DI: 7331791-VPS-A-00R-0005-BK

REF	Name	UDI-DI
7270	Provox Measure	07331791001710
7271	Provox Measure Flanges	07331791001727

Atos Medical AB compatible products:

None.