

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	DD	Pontus Eklund - X-PONEKL	2020-04-20 - 13:35
Reviewed:	DD	Jon Berg - JONBER	2020-04-20 - 14:57
Approved:	DD	Fredrik Calais - FRECAL	2020-04-20 - 16:59
Released:	DD	Pontus Eklund - X-PONEKL	2020-10-28 - 16:35

This document has been electronically signed by the persons above.

Product Information

Provox® TubeBrush


Product description:

The Provax TubeBrush is used for cleaning of the Provax LaryTube and Provax LaryButton ex situ. The Provax TubeBrush is packed 6 pieces in a plastic bag. It is available in two different models with outer diameter 8 mm or 12 mm.

Document No: 10000035860 Edition: 09 Release date: 2020-10-28

Product Information

Document ID:	PF052-01-TechInfo	Edition:	09
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
Classification: (EU) 2017/745	Class I, Rule 1		
Intended Use:	The Provox TubeBrush is used for cleaning of the Provox LaryTube and Provox LaryButton ex situ.		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	34883 (Airway device, cleaning brush, noninvasive).		
Sterilization:	Non-Sterile		
Raw material:	ABS, Stainless Steel, PBT and Cotton.		
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.		
Hazardous components:	None		
Expiration date:	3 years after manufacturing.		
Packaging:	6 pieces Provox TubeBrush are packed in a tamperproof plastic bag together with Instructions for Use.		

Product Information

Devices under Basic UDI-DI: 7331791-GEN-A-000-0001-E9

REF	Name	UDI-DI
7660	Provox TubeBrush 8 mm	7331791002656
7661	Provox TubeBrush 12 mm	7331791002663

Atos Medical AB Compatible products:

Range	BASIC UDI-DI
Provox LaryTube	7331791-LTU-0-000-0002-3E
Provox LaryButton	7331791-LTU-0-000-0000-38
Provox LaryButton Sizer Kit	7331791-LTU-0-000-0001-3B

Released

Document No: 10000035860 Edition: 09 Release date: 2020-10-28