| Justification: | Function: | Electronic signature justification: | Signed: Date (yyyy-mm-dd) - Time (hh:mm): |
|---|---|---|---|
| Issued: | QA | Abdallah Almashharawi - ABDALM | 2023-03-06 - 12:50 |
| Reviewed: | QA | Karolina Nilsson - KARNIL | 2023-03-07 - 15:40 |
| Approved: | QA | Elin Andersson - ELIAND | 2023-03-08 - 08:03 |

This document has been electronically signed by the persons above.

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# Product Information

## Provox® Silicone Glue


**Product description:**

Provox® Silicone Glue is a liquid glue that can be used to improve the adhesion between the skin and the adhesive.

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# Product Information

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|---|---|---|---|
| **Document ID:** | PF013-01-TechInfo | **Edition:** | 13 |

**Manufacturer:**
Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

**Classification: (EU) 2017/745** Class I, Rule 1

**Intended Use:** To reinforce attachment of Provox Adhesive base plates to intact skin around the tracheostoma.

**Use specifications:**

**Intended medical indication**
Product for rehabilitation for patients breathing through a tracheostoma.

**Intended patient population**
Patients of any age.
Cognitive ability, by a clinician judged as sufficient.
Manual dexterity, by a clinician judged as sufficient.

**Intended usage**
Single patient multiple use, Over-the-counter.

**Intended part of the body/type of tissue applied to or interacted with**
The device will contact intact skin and mucosal membrane.

**Intended user profile**
The product is supposed to be handled by the patient but is also handled by physicians, trained nurses, SLPs, clinicians and caregivers.

**Intended conditions of use (i.e. environment including hygienic requirements, frequency of use, location, mobility)**
Environment: Home use (normal daily environment without any or environmental restrictions regarding temperature, moisture etc.).
Outpatient clinic use. Hospital use.
Frequency of use: Continuous use.

**Contraindications:** Should not be used if the patient has hypersensitive or damaged skin, or known allergies against ingredients.

**CE Mark:** Yes. Devices are CE-marked.

**GMDN code:** 58978 (Synthetic-polymer liquid barrier dressing, nonsterile)

**Sterilization:** Non-sterile

**Raw material:** Silicone in solvent.
MSDS: DOW CORNING™ MG-2401 Silicone Adhesive

**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.

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# Product Information

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| **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:** | 2 years after manufacturing. |
| **Packaging:** | The glue is bottled in a glass bottle. The bottle is packed in a cardboard box together with Instructions for use. |

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# Product Information

**Devices under Basic UDI-DI:** 7331791-GEN-A-000-0003-EF

| REF | Name | UDI-DI |
|---|---|---|
| 7720 | Provox Silicone Glue | 07331791002984 |
| 7720-18 | Provox Silicone Glue | 07331791014789 |

**Atos Medical AB compatible products:**

| Range | BASIC UDI-DI |
|---|---|
| Provox StabiliBase | 7331791-ADH-0-000-0000-CQ |
| Provox XtraBase | 7331791-ADH-0-000-0000-CQ |
| Provox FlexiDerm | 7331791-ADH-0-000-0000-CQ |
| Provox OptiDerm | 7331791-ADH-0-000-0000-CQ |
| Provox StabiliBase OptiDerm | 7331791-ADH-0-000-0000-CQ |
| Provox Life Standard | 7331791-ADH-0-000-0001-CT |
| Provox Life Sensitive | 7331791-ADH-0-000-0001-CT |
| Provox Life Stability | 7331791-ADH-0-000-0001-CT |
| Provox Skin Barrier | 7331791-ADH-A-000-0004-UL |
| Provox Adhesive Remover | 7331791-ADH-A-000-0005-UP |
| Provox Cleaning Towel | 7331791-ADH-A-000-0003-UH |
| Provox Adhesive Strip | 7331791-ADH-A-000-0002-UE |