

## Cushion Nima Luft

Foam cushion with a spring cassette under the ischial tuberosities and a 3D mesh cover



### Intended use

Pressure relieving seat cushion for users who need shock absorption under the ischial tuberosities combined with soft, airy seating. The cushion consists of several foam layers with a spring cassette (X pocket) integrated under the ischial tuberosities — the springs give damping under load and contribute to air permeability. The 3D mesh cover is a spacer fabric cover that gives added comfort, carries heat and moisture away from the seating surface and reinforces the cushion's airiness. The cushion is therefore particularly suitable for heat-sensitive users or users with moisture problems at the seating surface.

**Use environment:** primarily wheelchairs; can also be used in other seating. The cushion is bevelled at the underside so it fits both flat and hammock seats. **Users:** the user themselves, or care staff/relatives following a needs assessment by a licensed prescriber. The cushion is delivered ready to use — no setting or adjustment needed.

### Construction

Four layers: a 3D mesh spacer fabric cover (air-permeable); a top layer of high-elastic polyether 50 kg/m<sup>3</sup>; a spring cassette (X pocket) under the ischial tuberosities for shock absorption and airiness; and an underlayer of firmer polyether plus cellular polyethylene at the bottom for stiffness. Height 9.5 cm.

### How to use the cushion

1. Take the cushion out of its packaging.
2. Place the cushion according to the labelling — the cover's **BAK** (back) and side labels indicate direction.
3. Check the size — choose another size if the cushion does not fit.
4. The cushion is ready to use — no adjustment needed.

### Reconditioning & care

**Between users:** wipe the cushion base with disinfectant or a 40 °C soap solution. Do not machine wash the cushion base.

**Drying:** dry the base flat in a drying cabinet or lying freely.

**3D mesh cover:** machine wash 60 °C; tumble-dry and drying-cabinet safe.

**Disposal:** a worn-out cushion is sorted as combustible waste.

### Important to keep in mind

- **Place the cushion correctly according to the labelling** — check front/back and up/down.
- User weight varies with size — check the table below.
- Inspect the cushion and the skin regularly.

|                     |                                                                 |
|---------------------|-----------------------------------------------------------------|
| <b>User weight</b>  | Max 150 kg (≤ 45×45) · Max 200 kg (sizes above 45×45)           |
| <b>Height</b>       | 9.5 cm (measured 5 cm in from the front edge, under the thighs) |
| <b>Weight</b>       | 1–2.5 kg depending on size                                      |
| <b>Service life</b> | Expected 5 years · Warranty 2 years                             |

### Accessories

- Standard 3D mesh cover (*included*)
- Incontinence-protected cover
- Hygiene cap

CE MD



Base:



Cover:



See page 2 for symbol explanations and full MDR info.

## Technical documentation and MDR information

Supplementary regulatory information under Regulation (EU) 2017/745 on medical devices (MDR). Intended use, construction, user weight, accessories and care are stated on page 1.

### Product identification and classification

**Article number format:** NIMALsbds (where sb = seat width, sd = seat depth in cm — e.g. NIMAL4545).

**ISO code:** 04 33 03 — Pressure relieving seat cushion.

**Classification:** Class I medical device under MDR (EU) 2017/745, rule 1.

**Intended user:** the user, following a needs assessment by a licensed prescriber.

**UDI-DI:** Each size has its own UDI-DI per GS1 (GTIN). Example: NIMAL4545 → GTIN 7350052868749.

**Barcode:** EAN-13.

**Sterile/reuse:** Non-sterile; reusable between users after reconditioning as instructed on page 1.

### Testing and standards

**Fire tested per:** ISO 7176-16 (resistance to ignition of upholstered wheelchair parts).

**Symbols:** Labelling per EN ISO 15223-1 (medical devices) and ISO 3758 (textile care).

**Quality management:** Manufactured under ISO 13485.

**Declaration of conformity:** The manufacturer has issued an EU declaration of conformity — contact Nimacare AB for the current version.

### Restrictions

- Users with an **existing category 3 or 4 pressure ulcer** on the seating surface — require assessment by a licensed prescriber before use.
- User weight exceeding the permitted limit for the size in question (see page 1).
- Use of a damaged cushion.

### Storage, inspection and environment

- Inspect the cushion and cover regularly — a damaged product must not be used.
- Avoid use near open flames or strong heat sources.
- Store cool and dry. Avoid prolonged direct sunlight.
- Do not use solvents for cleaning.

### Modification

The cushion must **not be cut down**. If another size is needed — choose another size from the range. Modification or cutting voids the CE marking and releases the manufacturer from liability.

### Residual risks

As with all seat cushions, a risk of pressure injury remains with prolonged uninterrupted loading or if skin checks are omitted.

**Incorrect size or orientation** can increase the risk of pressure injuries, unstable sitting and malpositioning. Users with reduced sensation or circulation require particular follow-up.

### Reporting of serious incidents

Serious incidents related to the use of this product must be reported to Nimacare AB ([info@nimacare.se](mailto:info@nimacare.se)) and to the competent authority of the Member State where the user and/or patient is established. In Sweden, incidents are reported to the **Swedish Medical Products Agency (Läkemedelsverket)** ([www.lakemedelsverket.se](http://www.lakemedelsverket.se)).

### Manufacturer and regulatory contact

#### Nimacare AB

Sigurdvägen 4, 18254 Djursholm, Sverige

SRN (EUDAMED): SE-MF-000050989

Tel: +46 (0)70 635 50 70 · E-mail: [info@nimacare.se](mailto:info@nimacare.se) · Web:

[www.nimacare.se](http://www.nimacare.se)

Person responsible for regulatory compliance (PRRC) under MDR Art. 15 — contact [info@nimacare.se](mailto:info@nimacare.se).

### Symbol explanations

Medical device symbols per **EN ISO 15223-1**. Wash and care symbols per **ISO 3758**.



Medical device



Consult instructions for use



**Wipe clean** — base only, no machine wash



**Dry flat** — cushion base dried flat



CE marking — complies with MDR (EU) 2017/745



Manufacturer



**Machine wash 60 °C** — cover only



**Tumble dry allowed** — cover, normal temperature

**Document information:** This product sheet constitutes both product information and instructions for use in paper form per MDR (EU) 2017/745, Annex I, section 23. Latest revision: 2026-07-30. Document ID: NIMA-NIMAL-EN-IFU-Rev2026-07-30. If this version differs from a later version published at [www.nimacare.se](http://www.nimacare.se), the later version applies. The product is UDI-DI labelled — check that the UDI on the label matches the delivery.