

Comfort cushion Nima Relax

Comfortable fibre cushion for pain-sensitive users — soft, light and versatile



Intended use

Nima Relax is a soft comfort cushion of siliconised hollow fibre that gives extra soft relief where it is needed — for users who are pain-sensitive or need soft support or added comfort against sensitive parts of the body. **Multifunctional:** can be used as a seat cushion, back support, or as soft support under other sensitive body parts. Light and easy to carry when moving about.

Ways to use: on top of a seat as a soft extra layer, as a soft back support, under the heel or other sensitive body parts that need soft support. Can also be used as a free-standing cushion in other seating. **Use environment:** home environments, care homes, hospitals and other care settings. **Users:** the user themselves, care staff or a relative.

Construction

Very soft fibre cushion filled with siliconised hollow fibre, with a cover of 100 % polyester. The airy hollow-fibre filling gives high comfort, soft support and reduced local pressure against sensitive body parts. Contributes to a pleasant microclimate through good air permeability that helps carry heat and moisture away. Height approx. 5 cm. Very light to carry when moving about. Available in three sizes: 33×33, 40×40 and 45×45 cm.

How to use the cushion

1. Take the cushion out of its packaging.
2. Place the cushion where you need soft support — in the seat, against the back, or under another body part.
3. The cushion is ready to use — no settings needed.

Reconditioning & care

Whole cushion: machine wash 60 °C. Tumble-dry safe.

Between users: machine wash the whole cushion before the next user.

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

Important to keep in mind

- The cushion must **not be cut or modified** — doing so voids the CE marking.
- Inspect the skin regularly during prolonged sitting. Soft seating does not replace regular repositioning.

Sizes	33×33 cm · 40×40 cm · 45×45 cm
Height	Approx. 5 cm
Material	Filling: siliconised hollow fibre · Cover: 100 % polyester
Service life	Expected 5 years · Warranty 2 years

Article numbers

- NIMAREL3333 — 33×33 cm
- NIMAREL4040 — 40×40 cm
- NIMAREL4545 — 45×45 cm



Whole cushion:



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 numbers: NIMAREL3333 (33×33 cm) · NIMAREL4040 (40×40 cm) · NIMAREL4545 (45×45 cm).

Product type: Soft fibre cushion for comfort and support.

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

Intended user: the user themselves, care staff or a relative.

UDI-DI: Each size has its own UDI-DI per GS1 (GTIN). Example: NIMAREL4545 → GTIN 7350052860989.

Barcode: EAN-13.

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

Testing and standards

Materials tested per: SS-EN 1021-1 (smouldering cigarette) and SS-EN 1021-2 (open flame).

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.
- 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 or modified** — doing so 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) 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).

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 · Web:

www.nimacare.se

Person responsible for regulatory compliance (PRRC) under MDR Art. 15 — contact 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



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



Manufacturer



Machine wash 60 °C — whole cushion



Tumble dry allowed — 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-RELAX-EN-IFU-Rev2026-07-30. If this version differs from a later version published at www.nimacare.se, the later version applies. The product is UDI-DI labelled — check that the UDI on the label matches the delivery.