



Human Handling Concept



EU DECLARATION OF CONFORMITY

Name and address of the firm: master care A/S,
Sofienlystvej 3, 8340 Malling, Denmark

Single Registration Number (SRN): DK-MF-000011791

We, as the manufacturer, declare that we have issued this EU declaration of conformity under our sole responsibility and that the products listed below, all class 1 according to annex VIII of MDR 2017/745 – rule 1, meets all the provisions of the MDR 2017/745 which apply to conformity assessment procedure MDR Art. 52 & Annex II, III (Class I).

Classification: Medical Device, Classification 1.

Product name: Master Comfort Positioning Cushion,
Master Comfort Arm Cushion,
Master Comfort Cylinder Cushion,
Master Comfort Sleep,
Master Comfort Heel.

Basic-UDI-DI: 57440019763853RL

Article no.:

MC 001-8012*, MC 001-8013*, MC 001-8014*, MC 001-8015, MC 001-8017, MC 001-8018, MC 001-8019, MC 001-8020, MC 001-8021, MC 001-8022*, MC 001-8023*, MC 001-8024*, MC 001-8025, MC 001-8026*, MC 001-8030, MC 001-8031*, MC 001-8080, MC 001-8081*, MC 001-8085, MC 001-8086*, MC 001-8090, MC 001-8091*, MC 001-8095, MC 001-8096*.

(*Cotton cover for main product)

Intended use:

The products can be used by people who have impaired or partial impaired capacity to change body position due to restricted movement or body perception damage and therefore are unable to provide a stable body positioning without support. Furthermore, the products can prevent/ reduce injuries caused by pressure or shearing forces for users who are in risk of pressure or shear ulcers.

The products can also have a stabilizing and calming effect on people with sensory or cognitive impairments and have a pain-relieving effect.

The products increase the support surface, which gives a better distribution of the pressure on the tissue thereby reducing the risk of pressure injuries.

Declaration's validity:

5 years after signing or changes to the technical documentation.

Date of Issue and place: Malling, 15.01.2025

Name and function:



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