



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 for people with restricted movement of their own body to provide stability and support. Furthermore, the product can prevent/ reduce injuries caused by pressure or shearing forces. They 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:

 **master care**
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