



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:

One Time Lift

Basic-UDI-DI:

57440019763018DS

Article no.:

MC 001-1420

Intended use:

The product is a combined Single Patient Use Lifting Sling and Turning system which reduces friction between the user and the mattress, making it easier for the helper and more gently for the user whilst turning in the bed. This product should always be used in combination with a One Time Cover or a Mattress Cover from master care A/S. The product should not be used if it is or has been wet since this degrades the breaking strength of the product.

Testing:

Approved ISO 10535:2006, 17.09.2013

Declaration's validity:

5 years after signing or changes to the technical documentation are made.

Date of Issue and place: Malling, 15.01.2025

Name and function:



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Vidar Geitheim, CEO