



Human Handling Concept

C E 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:

Nylon Master Open /Tube

Basic-UDI-DI:

57440019763823RB

Article no.:

MC 001-1103, MC 001-1104, MC 001-1203, MC 001-1204

Intended use:

The Nylon Master Open and Tube serve to transport the insured as gently as possible or the insured person in or out of bed.

The products are designed to be used in two layers to reduce friction for users with limited function during bed transfers. The products can reduce the risk of shear injuries. The products are suitable for use at home by healthcare professionals or private carers who have been trained in the use of the product.

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:

www.kitstetysphe.dk

Vidar Geitrheim, CEO

mastercare