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H u m a n H a n d l i n g C o n c e p t



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:

X-Ray

Basic-UDI-DI:

57440019763813R8

Article no.:

MC 004-6000, MC 004-6001, MC 004-6002, MC 004-6003, MC 004-6009, MC 004-6010, MC 004-6011, MC 004-6013, MC 004-6014, MC 004-6015, MC 004-6016, MC 004-6017

Intended use:

The product is used when positioning the x-ray cassette under the patient while in supine position.
The purpose is to slide the detector gently under an immobile patient.

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:

 **mastercare**
HUMAN HANDLING SYSTEM
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Vidar Geitrheim, CEO