

EG – Declaration of Conformity

pursuant to Directive 2017/745 Annex I General Safety and Performance Requirements and Annex II/III Technical documentation and on post-market surveillance on medical devices (MDR)

We:

OMNI-PAC Ekco GmbH Packaging Materials
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Germany
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declare, under its sole responsibility, that the **collection of CareBowl and CareTainer** listed on page 2 comply with the relevant provisions of Directive 2017/745 Annex I/II/III on medical devices (MDR).

Classification: Class I according to the 2017/745 Annex VIII:

Rule 1: non-invasive, non-sterile, without measuring function

It is confirmed that the products are free of

- tissues of animal origin
- pharmaceutical ingredients
- derivatives of human blood.

The products do not contain phthalates, latex or substances which are carcinogenic, mutagenic or toxic to reproduction and comply with the requirements of Annex I to Directive 1272/2008 (CLP). The products contain at least 95% recycled fibres.

Batch number: see label on the packaging

In accordance with Annex V, the CE marking is affixed in the following way:

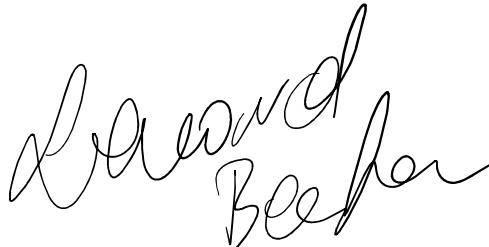


THIS DECLARATION IS VALID UNTIL 28.07.2022.

Scunthorpe , the 28.07.2021

Place and date of issue

Safety Officer for Medical Devices- Beata Lenard



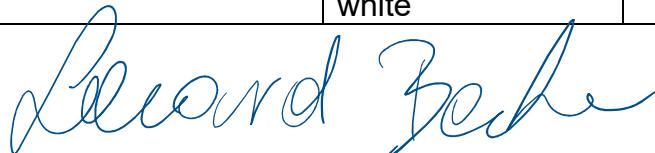
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Basic UDI-DI for all products is: 426067659 001 BT

Nr.	UDI-DI	Article list trays REF (article number)	Product name	size
1	4260676590014	18BMEDIX300D	CareBowl 300 grey	300
2	4260676590021	18AMEDIW300D	CareBowl 300 white	300
3	4260676590038	187MEDW65/D01	CareTainer 65 white	1240
4	4260676590045	187MEDW73/D01	CareTainer 73 white	840
5	4260676590052	187MEDW35/D01	CareTainer 35 white	840
6	4260676590069	187MEDW75/D01	CareTainer 75 white	450
7	4260676590076	187MEDW70/D01	CareTainer 70 white	1200
8	4260676590083	187MEDW33/D01	CareTainer 33 white	840
9	4260676590090	187MEDW25/D01	CareTainer 25 white	1320

Scunthorpe , 28.07.2021
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