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
Am Tidehafen 5
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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:

CE

THIS DECLARATION IS VALID UNTIL 21.02.2023.

Scunthorpe , the 21.02.2022
Place and date of issue

Safety Officer for Medical Devices- Beata Lenard

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 , 21.02.2022
Place and date of issue

Safety Officer for Medical Devices -Beata Lenard