

 <p>OMNI-PAC GROUP The natural choice</p>	<h1>Declaration of Conformity</h1>	
		Page 1/2

**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  
26931 Elsfleth  
Germany  
Phone: (+49) 4404 925 178  
Fax: (+49) 4404 925 199

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

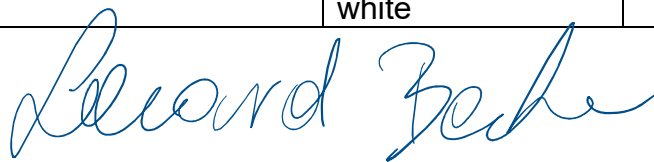


 <p><b>OMNI-PAC</b> GROUP <i>The natural choice</i></p>	<b>Declaration of Conformity</b>		
		Page 2/2	

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

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

Scunthorpe , 28.07.2021  
Place and date of issue



Safety Officer for Medical Devices -Beata Lenard