EU Declaration of Conformity

Company Name, registered trade name or registered trademark	OMNI-PAC Ekco GmbH Packaging Materials
SRN of the manufacturer	DE-MF-000006833
Address of your registered office where you can be reached and where you are actually located	Am Tidehafen 5 26931 Elsfleth Germany Phone: (+49) 4404 925 178 Fax: (+49) 4404 925 199
A declaration that the manufacturer bears sole responsibility for the issuance of the EU Declaration of Conformity	We, OMNI-PAC Ekco GmbH, declare that the issuing of this Declaration of Conformity is our sole responsibility.
The Basic UDI DI according to Annex VI Part C MDR	426067659 001 BT
Product name and trade name, product code, catalogue number or any other unique reference enabling the identification and traceability of the product covered by the EU Declaration of Conformity	Caretrays Tradenames: CareBowl, CareTainer Product Variants/Tradenames as listed below on second page.
Purpose	The device is intended to support patient treatment or care workflows, requiring possibility to store body expulsions or instruments for later processing, mainly disposal or cleaning.
The risk class of the product according to the rules described in Annex VIII MDR	Class I according to Rule 1
An assurance that the product covered by this declaration complies with the underlying Regulation and any other relevant Union legislation which provides for the issuance of an EU declaration of conformity	We hereby declare that our product Caretrays complies with all applicable requirements of EU Regulation 2017/745/EU on medical devices (MDR)
References to further regulations or common specifications for which conformity is declared	The product does 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.
Where appropriate, the name and identification number of the notified body, a description of the conformity assessment procedure carried out and a marking of the certificate(s) issued	We carried out conformity assessment procedure in accordance with MDR Annex V incl. I/II/III/IV in accordance to risk class I. No notified body or certification required.
Additional information (if any)	We have established an ISO 9001 certified and MDR Article 10(9) compliant Quality Management System.
Name and function of the signatory as well as information for whom and in whose name this person signed	Beata Lenard, Safety Officer for Medical Devices –

The above-mentioned product is a medical device according to MDR article 2 (1).

It fulfils the general safety and performance requirements according to Annex I of the MDR.

The conformity has been established by means of the above-mentioned conformity assessment proc edure.

The underlying provisions of the MDR, the state of the art and above mentioned other regulations or common specification were met.

The declaration is valid with the date of the signature below.

Scunthorpe, 02.08.2022

EU Declaration of Conformity

The above-mentioned product refers to the below listed items/variants/tradenames.

No.	UDI-DI	Product List REF (Item No.)	Variant/Tradename	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 grey	1320

Items can be identified by batch number (UDI-PI) on product label indicating manufacturing date enabling clear reference to this declaration of conformity. Product labels contain all required marks and information including CE affixed in the following way.

CE

Scunthorpe, 02.08.2022