

	Declaration of Conformity	CDL-Omnipac GmbH
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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 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 product **CareBowl L** 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 31.12.2021.

Elsfleth, the 22.06.2021

Place and date of the exhibition

Safety Officer for Medical Devices, Dipl. Biol. Dirk Schultzen

 OMNI-PAC GROUP <i>The natural choice</i>	Declaration of Conformity	CDL-Omnipac GmbH
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Basic UDI-DI for all products is: 426067659 001 BT

Nr.	UDI-DI	Artikelliste Auffangschalen REF (Artikelnummer)	Produktbezeichnung	size
1	4260676590014	18BMEDIX300/D33	Medimex/CareBowl L grau 300	300

Elsfleth, den 22.06.2021
Ort und Datum der Ausstellung

i.V. Dirk Schultzen



Sicherheitsbeauftragte für Medizinprodukte, Dipl.-Biol. Dirk Schultzen