

5000-8012 OTAL® disposable hand pump, delivery tubes PE  
5005-8012 OTAL® disposable foot pump, delivery tubes PE  
5000-8000 Delivery tubes PE for OTAL® disposable pump, Ø 12mm

## Declaration of Conformity

of parts coming in contact with the medium (tubes)

### European Union (EU) Food Contact

Our supplier confirms that The monomer(s) and the additive(s) of this resin are listed in Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and all its Amendments.

This product was tested for the overall and specific migration compliance per Commission Regulation (EU) No 10/2011. The tested sample thickness was 3.175 mm (125 mils). The surface-to-volume ratio was 1 dm<sup>2</sup> sample immersed in 1dl simulant. For measuring the overall migration level, this product was tested with 3% acetic acid for 10 days at 40°C, with 50% ethanol for 10 days at 40°C, and with olive oil for 10 days at 40°C. For measuring the specific migration level, this product was tested with 3% acetic acid for 10 days at 60°C, with 50% ethanol for 10 days at 60°C, and with olive oil for 10 days at 60°C. This product complies with the overall migration limit (OML) and specific migration limits (SML).

This product does not contain any dual-use additive per Regulation (EC) No 1333/2008 and its Amendments.

This product meets the requirements of Framework Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food. This product meets the requirements of Plastic Regulation (EU) No 10/2011 Article 19 and the requirements on NIAS.

This product is produced in accordance with good manufacturing practice (GMP) as outlined in EU GMP Regulation (EC) No 2023/2006.

### U.S. FDA Food Contact

This product meets the requirements for polyolefin resins intended for food packaging applications as described in the FDA olefin polymer regulations 21 CFR 177.1520(c) 3.2a. The resin may be used in contact with all types of food as defined in Table 1, 21 CFR 176.170(c) and at use conditions B-H as defined in Table 2, 21 CFR 176.170(c).

This product is produced in accordance with good manufacturing practices (GMP) as outlined in 21 CFR 174.5.

The declaration is based on our current state of knowledge and information provided by our supplier at the time that the document was drawn up. The supplier – Bürkle GmbH in Bad Bellingen/Germany – is certified according to the standard DIN EN ISO 9001 by the DQS (German Society for Quality Assurance) since 1995. The number of the certificate is 2284-08.

31. January 2019



Bürkle GmbH, Bad Bellingen,  
Martin Saint-Denis, Managing Director

