

DECLARATION OF CONFORMITY - EU WASTE

PLASTIC FLEXIBLE PACKAGING - OTHER (OFTEN POLYCARBONATE OR ABS)

Ultradent Products Inc, has evaluated this packaging by using Articles 5 to 12 of the Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste, and confirms that this packaging is compliant with the requirements of Article 39 of the Regulation (EU) 2025/40. Design documentation can be requested through the Regulatory Affairs Department.

Manufacturer: Ultradent Products Inc.,
505 West Ultradent Drive (10200 South),
South Jordan, UT, 84095

EU Authorized Representative: Ultradent Products GmbH
Am Westhover Berg 30
Cologne, Germany 51149

Packaging Identification	Level: Secondary Type: Plastic Flexible Packaging Material: Other (often polycarbonate or ABS)
Description of packaging	Plastic Film
Conformity to other relevant Union harmonization legislation / relevant harmonized standards or technical specifications	Regulation (EU) 2017/745 (MDR) EN ISO 13485:2016/AC:2018/A11:2021 - Medical devices - Quality management systems - Requirements for regulatory purposes

This Declaration of Conformity is issued under the sole responsibility of the manufacturer
Signed for and on behalf of: Ultradent Products, Inc.



Emma Gillespie
Regulatory Compliance Manager – Regulatory Affairs

03 August 2026

Date

South Jordan, UT, USA

Place of issue