

# DECLARATION OF CONFORMITY - EU WASTE

## PLASTIC FLEXIBLE PACKAGING - POLYVINYLCHLORIDE



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

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

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

  
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Emma Gillespie  
Regulatory Compliance Manager – Regulatory Affairs

03 August 2026  
\_\_\_\_\_  
Date

South Jordan, UT, USA

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Place of issue