

# EU Declaration of Conformity

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in accordance with Annex IV of Regulation (EU) 2017/745 on medical devices

## 1. Manufacturer Information

Manufacturer: Puhlmann Printing GmbH

Address: Moorenstraße 10, 45131 Essen, Germany

SRN: DE-MF-000048379

## 2. Product Information

Product name: Puhlmann Printing Dental Bite Pro Filament

Product type: 3D printing filament for the production of individual impression trays and bite registrations

Basic UDI-DI (GTIN): 4262483310021

Risk class: Class I according to MDR Annex VIII

UDI-PI (Batch number): e.g. 2505A (see packaging)

## 3. Declaration of Conformity

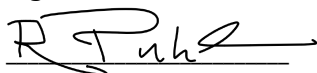
Puhlmann Printing GmbH hereby declares that the product described above meets all applicable General Safety and Performance Requirements as set out in Annex I of Regulation (EU) 2017/745. The conformity assessment was carried out under the sole responsibility of the manufacturer in accordance with Article 52(7) MDR, without the involvement of a Notified Body. The product is non-sterile, has no measuring function, and is not reusable. The CE marking has been affixed under the sole responsibility of the manufacturer.

## 4. Place, Date, Signature

Place: Essen, Germany

Date: 24.06.2025

Signature:



Robin Puhlmann

Managing Director – Puhlmann Printing GmbH