

Annex IV EU Declaration of Conformity

Manufacturer Name and Address: SpofaDental a.s.

Markova 238, 506 01 Jičín, Czech Republic

Single Registration Number (SRN) CZ-MF-000000945

Technical File Name/Number: TD F111

Basic UDI-DI: 859474710000132A

Product Tradename(s): Impression Compound

Device Identification: see Attachment 1

Classification and Rule(s): Class I, Rule 5 per Annex VIII of MDR 2017/745

Intended Purpose: Thermoplastic Impression Material

- intended for full or partial impressions, copper band impressions or for adding to the periphery of an impression tray.

Common Specifications: N/A

Notified Body: N/A

Notified Body Number: N/A

Conformity Assessment Procedure & Annex II, III, IV according to Article 52 (7) of EU MDR 2017/745

Certificate issued: N/A

Declaration Statement:

This declaration of conformity is issued under the sole responsibility of SpofaDental a.s.

We hereby declare that the above-mentioned device(s) comply with EU MDR 2017/745.

Signed for and on behalf of Manufacturer: SpofaDental a.s.

SpofaDental a.s.

Markova 238, CZ - 506 01 Jičín

IČO: 63999447

DIČ: CZ63999447

SpofaDental

-20-

A Kerr Company

Jičín

Place

15.4.2025

Date of Issue

Mgr. Jaroslav Adolf

Person Responsible for Regulatory Compliance

TD F111 Impression Compound - Attachment 1 to Annex IV EU Declaration of Conformity

REF	Description
00429	COMPOUND CAKES-RED 8 COUNT
00431	COMPOUND CAKES-RED 400 COUNT
00432	COMPOUND STICKS-RED 15 COUNT
00441	COMPOUND CAKES-GREEN 8 COUNT
00444	COMPOUND STICKS-GREEN 15 COUNT
00447	COMPOUND STICK-GREEN 500 COUNT
00452	COMPOUND CAKES-GREY 8 COUNT
00455	COMPOUND STICKS-GREY 15 COUNT