

## 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 Category:** Thermoplastic Impression Material

**Device Identification:** see Attachment 1

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

**Common Specifications:** N/A

**Notified Body:** N/A  
**Notified Body Number:** N/A  
**Conformity Assessment Procedure & Certificate issued:** Annex IV  
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.**

Jičín  
Place

06-03-2023  
Date of Issue

  
Mgr. Jaroslav Adolf  
Person Responsible for Regulatory Compliance

**SpofaDental a.s.**  
Markova 238, CZ - 506 01 Jičín  
IČO: 63999447  
DIČ: CZ63999447 **SpofaDental**  
A Kerr Company  
-19-

**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