

Annex IV EU Declaration of Conformity

Manufacturer Name and SpofaDental a.s.
IČ 63999447
Address: 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

18 -05- 2021

Date of Issue

Mgr. Jaroslav Adolf
Quality Manager

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

valid until 2023-03-05

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