SpofaDental
A Kerr Company

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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.

Jičín	06 -03- 2023	
Place	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
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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