

**Annex IV EU Declaration of Conformity**

**Manufacturer Name and Address:** SpofaDental a.s.  
IČ 63999447  
Markova 238, 506 01 Jičín, Czech Republic

**Single Registration Number (SRN)** CZ-MF-000000945

**Technical File Name/Number:** TD B113

**Basic UDI-DI:** 859474710000082H

**Product Tradename(s):** Elastic Cromo

**Device Category:** Alginate 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

valid until 2023-03-05

**SpofaDental**  
A Kerr Company

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**TD B113 Elastic Cromo - Attachment 1 to Annex IV EU Declaration of Conformity**

REF	Description
4221305PE	ELASTIC CROMO, 20x450g