

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 B113

Basic UDI-DI: 859474710000082H

Product Tradename(s): Elastic Cromo

Device Identification: see Attachment 1

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

Intended Purpose: Alginate impression material intended for all preliminary dental impressions.

Common Specifications: N/A

Notified Body: N/A

Notified Body Number: N/A

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

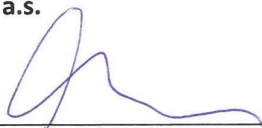
Declaration Statement:

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

REF	Description
4221305PE	ELASTIC CROMO, 20x450g

CONFIDENTIAL