

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 B103

Basic UDI-DI: 8594747100002027

Product Tradename(s): Repin

Device Category: Zinc Oxide – Eugenol 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

valid until 2023-03-05

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

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TD B103 Repin - Attachment 1 to Annex IV EU Declaration of Conformity

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