

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 C104

Basic UDI-DI: 859474710000052B

Product Tradename(s): Depural Neo

Device Identification: see Attachment 1

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

Intended Purpose: Slightly abrasive paste without fluoride intended for professional cleaning and polishing of the teeth by dental professionals.

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
SpofaDental
A Kerr Company
-19-

TD C104 Depural Neo - Attachment 1 to Annex IV EU Declaration of Conformity	
REF	Description
4816215PE	DEPURAL NEO, 75g