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 G101
Basic UDI-DI:	859474710000062D
Product Tradename(s):	**Duracrol**
Device Identification:	see Attachment 1
Classification and Rule(s):	**Class I**, Rule 5 per Annex VIII of MDR 2017/745
Intended Purpose:	Self-curing methacrylate resin indicated for manufacturing of custom trays and phantom models.
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
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 G101 Duracrol - Attachment 1 to Annex IV EU Declaration of Conformity	
REF	**Description**
4331302	DURACROL PLV. 500g
4331902	DURACROL LIQ. 250g

SpofaDental a.s.
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v Hradci Králové, oddíl B, vložka 2476

Banka: Deutsche Bank Aktiengesellschaft Filiale Prag
CZK: 3128700018/7910, IBAN: CZ4079100000003128700018, SWIFT: DEUTCZPX
Bank: Deutsche Bank AG, Berlin branch
EUR: 10070000/579589300, IBAN: DE11100700000579589300, SWIFT: DEUTDEBE