

Annex IV EU Declaration of Conformity

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

Technical File Name/Number: TD G101

Basic UDI-DI: 859474710000062D

Product Tradename(s): Duracrol

Device Category: Self-curing methacrylate resin for manufacturing of custom trays

Device Identification: see Attachment 1

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

Common Standards: EN ISO 13485, EN ISO 14971, EN ISO 15223-1, EN 1041, EN 1641, EN ISO 10993-1, EN ISO 10993-3, EN ISO 10993-5, EN ISO 10993- 10, EN ISO 10993- 11, EN ISO 10993- 12, EN ISO 7405, EN 62366-1

Notified Body: TÜV NORD CERT GmbH
Notified Body Number: 0044
Conformity Assessment Certificate issued: Annex IX
ISO certificate 44 221 141788 valid until 2023-03-05

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

10 -08- 2020

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
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SpofaDental
A Kerr Company

TD G101 Duracrol - Attachment 1 to Annex IV EU Declaration of Conformity	
REF	Description
4331302	DURACROL PLV. 500g
4331902	DURACROL LIQ. 250g