

Annex VII EC Declaration of Conformity

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

Technical File Name/Number: TD A107

Product Tradename: Evicrol

Device Category: Chemically-cured macrofilled composite

Device Identification: see Attachment 1

Classification and Rule: Class IIa, Rule 5 per Annex IX of the Council Directive 93/42/EEC

Notified Body: TÜV NORD CERT GmbH
Notified Body Number: 0044
Conformity Assessment Procedure & Certificate Issued: Annex II, CE certificate 44 232 141788, Edition 3

Declaration Statement:

We hereby declare that the above-mentioned device(s) comply with Council Directive 93/42/EEC.

Regulatory Affairs Signature:

08 -10- 2020

Issue date:


Name: Mgr. Jaroslav Adolf
Title: Quality Manager

valid until 2024-05-26

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

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TD A107 Evicrol - Attachment 1 to Annex VII EC Declaration of Conformity

REF	Description
4121121PE	Evicrol