

## 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 R087

**Basic UDI-DI:** 8594747100001126

**Product Tradename(s):** F.I.T.T.

**Device Category:** Functional Impression Tissue Toner

**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

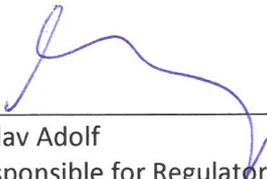
### Declaration Statement:

*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

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  
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TD R087 F.I.T.T. - Attachment 1 to Annex IV EU Declaration of Conformity	
REF	Description
61127	FITT Standard Pack
61132	FITT Liquid "Only" Package
61144	FITT Powder "Only" Package