SpofaDental
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# Annex IV EU Declaration of Conformity

| | |
|---|---|
| **Manufacturer Name and Address:** | SpofaDental a.s.<br>IČ 63999447<br>Markova 238, 506 01 Jičín, Czech Republic |
| **Single Registration Number (SRN)** | CZ-MF-000000945 |
| **Technical File Name/Number:** | TD B115 |
| **Basic UDI-DI:** | 859474710000222B |
| **Product Tradename(s):** | **Stomaflex** |
| **Device Category:** | Condensation Silicon Impression Material |
| **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<br>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 | 18 -05- 2021 | Mgr. Jaroslav Adolf<br>Quality Manager |
|---|---|---|
| Place | Date of Issue | |

valid until 2023-03-05

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

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| TD B115 Stomaflex - Attachment 1 to Annex IV EU Declaration of Conformity | |
|---|---|
| **REF** | **Description** |
| 4215110PE | STOMAFLEX PUTTY, 1300g |
| 4215310PE | STOMAFLEX LIGHT, 130g |
| 4215330PE | STOMAFLEX GEL CATALYST, 60g |

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