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 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 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, EN ISO 4823
Notified Body:	TÜV NORD CERT GmbH
Notified Body Number:	0044
Conformity Assessment	Annex IX
Certificate issued:	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	10 -08- 2020	Mgr. Jaroslav Adolf Quality Manager
Place	Date of Issue	

valid until 2023-03-05

SpofaDental a.s.
Markova 238, CZ - 506 01 Jičín
IČO: 63999447
DIČ: CZ63999447
SpofaDental
-19-

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

SpofaDental a.s.
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DIČ CZ63999447
zapsaná v OR vedeném Krajským soudem 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: DEUTDEBB