

Annex IV EU Declaration of Conformity

Manufacturer Name and	SpofaDental a.s. IČ 63999447
Address:	Markova 238, 506 01 Jičín, Czech Republic
Single Registration Number (SRN)	CZ-MF-000000945
Technical File Name/Number:	TD B107
Basic UDI-DI:	859474710000282P
Product Tradename(s):	Ypeen
Device Category:	Alginate 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 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

18 -05- 2021

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
-19-
SpofaDental
A Kerr Company

TD B107 Ypeen - Attachment 1 to Annex IV EU Declaration of Conformity

REF	Description
4221115PE	YPEEN, 7x450g
4221130PE	YPEEN, 800g