

Declaration of Conformity

SpofaDental a.s., Markova 238, 506 01 Jičín, Czech Republic

IČ(Company Identification Number): 63999447
DIČ(VAT Taxpayer Number): CZ63999447

According to DIR 93/42/EEC:2007, Sect. 13 Par. 2 of Law 22/1997 Coll. as amended - of Technical Requirements for Products, according to Sect. 4 of Law 346/2003 Coll. as amended - of Medical Devices and according to the Decree of the Government 336/2004 Coll. determining the Technical Requirements for Medical Devices

the manufacturer hereby declares that

YPEEN - dental alginate impression material - powder, Class I
(according to Annex IX of the DIR 93/42/EEC:2007, rule 5)

Package: 800 g in PE vessel
1x 450 g in a bag
7x 450 g in a bag

conforms to the basic requirements and with ordinary use, it is safe for its purpose of use. The manufacturer has implemented measures to guarantee conformity of all medical devices introduced to the market, to their technical documents and to the basic requirements.

To evaluate the basic properties of the product in a specified manner, procedure according to Annex V of the DIR 93/42/EEC:2007 standard was applied, with the participation of the Notified Body ID. No. 0044, TÜV NORD CERT GmbH, Langemarckstr. 20, D-45141 Essen – certificate No. 44 221 141788 valid until 2017-12-04.

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

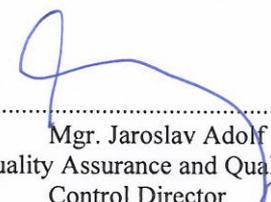
-17-

Jičín

10 -12- 2014

Stamp

Date


Mgr. Jaroslav Adolf
Quality Assurance and Quality
Control Director