

Declaration of Conformity

SpofaDental a.s., Markova 238, 506 46 Jičín, Czech Republic

IČO(Company Identification Number): 63999447
DIČ(VAT Taxpayer Number): CZ 63999447

According to DIR 2007/47/EEC, 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

ADHESOR FINE - zinc phosphate cement - powder/liquid, Class IIa
(according to Annex IX of the DIR 2007/47/EEC)

Original package: 80 g (80 g plv. in colours 1,2,3,4 and 55 g liq.)

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 prove conformity, the following regulations and harmonised Czech standards have been applied:

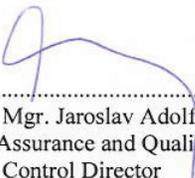
DIR 2007/47/EEC
ČSN EN 1641 Dentistry - Medical Devices for Dentistry - Materials
ČSN EN ISO 9917-1 Dentistry - Water-based cements - Part 1: Powder / liquid acid-base cements
ČSN EN ISO 10993-1 Biological Evaluation of Medical Devices - Evaluation and Testing

To evaluate the basic properties of the product in a specified manner, procedure according to Annex II of the DIR 2007/47/EEC standard was applied, with the participation of the Notified Body TÜV NORD – certificate No. 44 232 09 365388-001.

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01-12-2009


Mgr. Jaroslav Adolř
Quality Assurance and Quality
Control Director

Date