

## 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 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

**ADHESOR** - zinc phosphate cement - powder/liquid, class IIa

(according to Annex IX of the DIR 93/42/EEC:2007)

Package: 80 g plv. in colours 1,2,3,4 and 55 g liq. Normal  
separately 55 g liq. Normal  
separately 80 g plv. in colours 1, 2

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 93/42/EEC:2007 concerning medical devices  
DIR 2004/12/EC on packaging and packaging waste  
DIR 67/548/EEC The classification, packaging and labelling of dangerous substances  
ČSN EN 1641/2010 Dentistry - Medical devices for dentistry - Materials  
ČSN EN ISO 10993-1/2010 Biological evaluation of medical devices - Part 1:  
Evaluation and testing within a risk management process  
ČSN EN ISO 14971/2009 Medical devices - Application of risk management to medical devices  
ČSN EN 1041/2009 Information supplied by the manufacturer of medical devices  
ČSN EN 980/2009 Symbols for use in the labelling of medical devices  
ČSN EN ISO 9917-1/2008 Dentistry - Water-based cements - Part 1:  
Powder/liquid acidbase cements

To evaluate the basic properties of the product in a specified manner, procedure according to Annex II of the DIR 93/42/EEC:2007 standard was applied, with the participation of the Notified Body TÜV NORD – certificate No. 44 232 09 365388-001.

**SpofaDental a.s.**

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-17-

27 -01- 2012

Mgr. Jaroslav Adolř  
Quality Assurance and Quality  
Control Director

Date