

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

CARYOSAN - zinc oxide-eugenol dental cement - powder/liquid, Class IIa
(according to Annex IX of the DIR 93/42/EEC:2007, rule 5)

Original package: 60 g (30 g plv. Normal, 30 g plv. Rapid and 25 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 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 ISO 15223-1/2012 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
- ČSN EN ISO 3107/2011 Dentistry - Zinc oxide/eugenol cements and zinc oxide/noneugenol 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 ID. No. 0044, TÜV NORD CERT GmbH, Langemarckstr. 20, D-45141 Essen – certificate No. 44 232 09 365388-001 valid until 2014-12-04.

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

Jičín 27-03-2014

Date

Mgr. Jaroslav Adolf
Quality Assurance and Quality
Control Director