

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

DESIDENT CAVICIDE – disinfectant / decontaminant cleaner for dental and medical devices - Class IIa
(according to Annex IX of the DIR 2007/47/EEC)

Package: 200 ml of solution in PE bottle with mechanical spray
700 ml of solution in PE bottle with mechanical spray
5 l of solution in PE container


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


ISO 13485 /ISO 14971 /EN 980 / ISO 10993-1 / Law CR 22/1997 Sb. and 346/2003 Sb.
and Directive 336/2004 Sb.

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.


Mgr. Jaroslav Adolf
Quality Assurance and Quality
Control Director

01-12-2009

Date

SpofaDental a.s.
Markova 238, CZ - 506 46 Jičín
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IČ: 63 99 94 47
DIČ: CZ 63 99 94 47
zapsaná v OR vedeném Krajským soudem
v Hradci Králové, oddíl B, vložka 2476

Banka: Deutsche Bank
CZK: 31287000187910, IBAN: CZ4079100000003128700018
USD: 31287000097910, IBAN: CZ40791000000031287000300
EUR: 31287001087910, IBAN: CZ6979100000003128700108
SWIFT: DEUT22PX

MIRCEA NISAN
traducator autorizat
Sworn Translator
Aut. M. J. 12/2009

Traducere din limba engleză

SpofaDental

Declaratie de conformitate

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

ICO (Company Identification Number): 63999447

DIC (VAT Taxpayer Number): CZ 63999447

Conform DIR 2007/47/EEC, Sect 13 Par2 a legii 22/1997 Coll cu completarile ulterioare – privind Cerintele Tehnice ale Produselor, conform Sect. 4 a legii 346/2003 Coll cu completarile ulterioare – privind Dispozitivele medicale si in acord cu Decretul Guvernamental 336/2004 Coll, privind Cerintele tehnice ale Dispozitivelor Medicale,

producatorul declara prin prezenta ca

DESIDENT CAVICIDE – dezinfectant / decontaminant, pentru curatarea dispozitivelor medicale dentare – Clasa IIa (conform Anexei IX a directivei 2007/47/EEC)

Ambalaje: 200ml solutie in flacoane plastic cu spray mecanic
700ml solutie in flacoane plastic cu spray mecanic
5l solutie in flacoane plastic

Este in conformitate cu cerintele de baza si necesitatile de uz normal, prezinta siguranta pentru scopul de utilizare in care a fost creat. Producatorul a implementat si aplica masuri de garantare a conformitatii tuturor dispozitivelor medicale introduse pe piata cu documentatia tehnica si cerintele de baza.

Conformitatea este dovedita prin respectarea reglementarilor de mai jos si a standardelor cehe armonizate:

DIR 2007/47/EEC

ISO 13485 / ISO 14971 / EN 980 / ISO 10993-1 / Legea CR 22/1997 Sb si 346/2003 Sb si Directia 336/2004 Sb

Evaluarea proprietatilor de baza ale produsului in modul specificat, s-a aplicat procedura standard conform Anexei II a Directivei DIR 2007/47/EEC, cu participarea Organismului Notificat TUV NORD – Certificat nr. 44 232 09 365388-001.

semnatura indescifrabila

Manager Jaroslav Adolf

Data : 01.12.2009

Director Asigurarea si Controlul Calitatii

Stampila SPOFADENTAL a.s.

MIRCEA CHISAN
traducator autorizat
Sworn Translator
Aut.: M.J. 1050/999