



Declaration of conformity

According to § 13 paragraph 2 of Act No. 22/1997 Coll., On technical requirements for products, as amended (the Act) and Council Directive 93/42/EEC (as amended by 2007/47/EC) whose requirements are taken by Government Regulation No. 54/2015 Coll. (as amended) laying down technical requirements for medical devices.

Manufacturer: **GLOBAL DENTAL TRADING, s.r.o.**
Kryštofova 1015/17, 149 00 Prague – Haje, Czech republic
VAT.: CZ 289 71558

Declares that the products: **Dental amalgam capsules**
(Types : GT 400, GT 400 FAST)

Material: Dental amalgam alloy GT 400, GT 400 FAST, Hg sachets in the purity 99,999% and the plastic capsules

Application: Self-activation capsules dosed with alloy and dental mercury intended for mixing in the dental amalgamator in the practise of dentists, such as dental fillings and replacement of the anatomy of the tooth.

Encapsulation meets the requirements of the standard DIN EN ISO 20749 : 2017

Classification of a medical device: Class IIa (rule 8, paragraph 2.4.1)

This product meets the essential requirements of Annex 1, NV No. 54/2015 , and is in normal use for its purpose, secure, efficient and convenient. The manufacturer has taken measures to ensure conformity of the medical device placed on the market with its technical documentation and basic requirements. The product is prepared according to standard manufacturing procedures and in compliance with established procedures in the production and use does not pose a risk to the environment. Is identical with physical means, which is the subject of EC certificate No. 17 0607 QS / NB, issued by AO / 1023 Institute for Testing and Certification, as, Zlín, of 19.12.2017 valid to 18.12.2022.

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Ing. Dagmar Pravdová, manager

Prague 10.3.2020