



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Production Quality Assurance No. 17 0607 QS/NB

The quality system of manufacturer

Global Dental Trading, s.r.o.

Kryštofova 1015/17, 149 00 Prague – Háje, Czech Republic

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

for the following product category(ies):

Dental amalgam

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class IIb and Class III devices covered by this certificate, an EC Type-Examination Certificate according to MDD Annex III is required.

Valid from: 2017-12-19
Valid until: 2022-12-18
First Issued: 2017-12-19
Revision: -

Date: 2017-12-19



Paul Voj
RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



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Annex to EC Certificate No. 17 0607 QS/NB
issued for manufacturer:

Global Dental Trading, s.r.o.
Kryštofova 1015/17, 149 00 Prague – Háje, Czech Republic

Product(s):

Name: Dental amalgam capsule

Trade name(s): -

Model(s): GT400, GT400 FAST, GT500, GT600

Class: IIa

GMDN: 16367

Name: Dental amalgam alloy

Trade name(s): -

Model(s): GT400, GT400 FAST, GT500, GT600

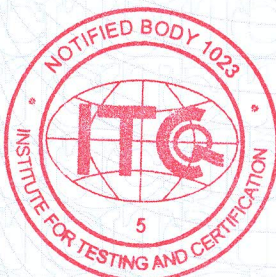
Class: IIa

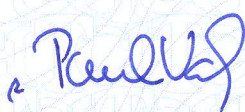
GMDN: 16367

Facility(ies):

Czech Amalgam s.r.o.,
Střednice 56, 277 24 Střednice, okres Mělník, Czech Republic

Date: 2017-12-19
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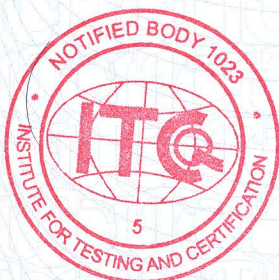
issued for manufacturer:


Global Dental Trading, s.r.o.
Kryštofova 1015/17, 149 00 Prague – Háje, Czech Republic

Certificate History:

Revision	Date	Reference Number	Action
	2017-12-19	803602622	Certification

Date: 2017-12-19
Revision: -




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