



Lloyd's Register
LRQA

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

**SAFINA a.s.
Víteňská 104,
252 42 Vestec
Czech Republic**

has been assessed against the requirements of Annex II of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ 0955761/C
Original Approval: 26 February 1997
Current Certificate: 5 February 2015
Certificate Expiry: 31 January 2018
LRQA Notified Body Number 0088


Issued by: Lloyd's Register Quality Assurance Limited

Hiramford, Middlemarch Office Village, Siskin Drive, Coventry, CV3 4FJ, United Kingdom.



**EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM
CERTIFICATE LRQ 0955761/C SCHEDULE**

**In accordance with the requirements of the Medical Devices
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK
Statutory Instrument 2002 No. 618**

**SAFINA a.s.
Víteňská 104,
252 42 Vestec
Czech Republic**

Class IIa Products

Dental High Gold Content Casting Alloys

Au 22 ct

Au 18 ct pt

Dental Reduced Gold Content Casting Alloys

Aurix L

Aurix L60

Aurosa

Palargen L

Argenpal IVA

Dental Base Metal Casting Alloy

Oralium

Dental Alloys with Reduced Content Silver

Koldan

Dental Alloys for Brazing

Palargen T Eko

Palargen M2

Safibond M

Safibond P

Safibond Plus P

Safibond Bio M

Safibond Bio P

Aurix M

Aurix T





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252 42 Vestec
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Class IIa Products

Amalgams

Safargam Special
Safargam NG2
Safargam Plus
Safargam Dentis 60
Dental Mercury

Dental Alloys for Metal-Ceramic Restoration

Safibond
Safibond Bio
Safibond Plus
Safibond Gold
Oralium Ceramic

Schedule Issue: 01
Date of Schedule Issue: 5 February 2015
LRQA Notified Body Number 0088

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