

**Intertek**

**AMTAC Certification Services**



# CERTIFICATE OF AUTHORIZATION

## MEDICAL DEVICES DIRECTIVE 93/42/EEC

*This is to certify that*

Company: **IMPLASA-HÖCHST GmbH**  
Situated at: **Rödelheimer Landstrasse 75-85**  
**60487 Frankfurt**  
**Deutschland**

has demonstrated compliance with Annex II of the Medical Devices Directive 93/42/EEC  
and is hereby entitled to use the CE 0473 Marking on those products listed below and  
as per attached schedule:

**DENTAL IMPLANT**

**Signed for and on behalf of ACSL**

Technical Manager:

Issue Date: 28 June 2006  
Expiry Date: 27 June 2011  
Certificate No: 727 CE



*Valid subject to continued compliance demonstrated at periodic surveillance and 3 yearly re-assessment!*

**Certificate Number**  
727 CE

**Initial Certification Date**  
28 June 2006

**Certificate Issue Date**  
21 April 2008

**Certificate Expiry Date**  
27 June 2011

*The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.*

*This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.*

*AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.*

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# EC Certificate

## FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC for Medical Devices, Annex II (3)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0473 marking on those products listed below.

### Organization:

## Implasa-Höchst GmbH

Rödelheimer Landstrasse 75-85, 60487 Frankfurt, Germany

### Dental implants and systems:

1. Pragmatic system implants (Gothic, Doublegothic, Nordic and Viking implants)
2. Romantic system implants (Romantic, Sweet implants)
3. Antic direct system (Antic, Ionic, Antic Ball and Elegant implants)

### Dental Implant accessories:

Surgical kits, drills, trepans, osteotomes, superstructure for Pragmatic and Romanitic (abutments and associated devices), implant analogue



Authorized Signatory

R. NASH

AMTAC Certification Services Limited, Milton Keynes, UK