



Certificate of Registration

The following organization's quality management system has been assessed and registered by AMTAC Certification Services Limited as conforming to the requirements of:

ISO 13485:2003

Certificate Number
475 C

Initial Certification Date
06 February 2006

Certificate Issue Date
18 July 2007

Certificate Expiry Date
05 February 2009

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 accredited body.

In the issuance of this certificate, AMTAC assumes no liability to any party other than to the Client and then only in accordance with the agreed Terms and Conditions.

AMTAC Certification Services Limited is an accredited body registered under UKAS with the identification number of 061.

AMTAC Certification Services Limited
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Email: ecsi@intertek.com

Organization:

WRIGHT HEALTH GROUP LIMITED

Kingsway West, Dundee DD2 3QD, Scotland

**The Quality Management System is applicable to Design and manufacture of:
Dental products as per attached schedule**



061

Authorized Signatory:

AMTAC Certification Services Limited, Milton Keynes, UK



PRODUCT SCHEDULE FOR CERTIFICATE 475 C WRIGHT HEALTH GROUP LIMITED

Dental materials to include the following:

- Artificial acrylic teeth
- acrylic denture base resin
- alginate impression materials
- Polystyrene impression trays
- Alginate impression trays adhesive
- Prophylaxis paste
- Plaster separator solution (sodium alginate)
- Hard surface disinfectant
- Surgical scrub
- Skin disinfectant
- General disinfectant
- Dye stone and plaster remover
- Special tray material germicidal pumice
- Wax pattern wetting agent

Original Issue Date: 06 February 2006

Authorized Signatory:

Certificate Issue Date: 18 July 2007

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Certificate Number
475 B CE

Initial Certification Date
29 October 2004

Certificate Issue Date
18 July 2007

Certificate Expiry Date
28 October 2009

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

PRODUCTION QUALITY ASSURANCE
Directive 93/42/EEC for Medical Devices, Annex V

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

Organization:

WRIGHT HEALTH GROUP LIMITED

Kingsway West, Dundee DD2 3QD, Scotland

Monarch range of acrylic teeth



Authorized Signatory:

AMTAC Certification Services Limited, Milton Keynes, UK