EC Certification



FULL QUALITY ASSURANCE SYSTEM Directive 93/42/EEC for Medical Devices, Annex II (OBL)

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 of the Directive 93/42/EEC on medical devices via an Own Branding arrangement. We certify that the full 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.

HENRY SCHEIN INC

135 Duryea Road, Melville, New York 11747, USA

Medical and dental devices as per the attached schedule

Certificate Number:150 B CEInitial Certification Date:19 October 2006Certificate Effective Date:23 August 2013Certificate Expiry Date:18 October 2016

Brian Johnson ~ Authorised Signatory

AMTAC Certification Services Limited, Milton Keynes, UK This certificate is the property of AMTAC Certification Services Ltd a wholly owned subsidiary of Intertek Holdings Ltd

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at <u>certificate.validation@intertek.com</u> or by scanning the code to the right with a smartphone.

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.

The certificate remains the property of Intertek, to whom it must be returned upon request.

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.

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

AMTAC Certification Services Limited, Davy Avenue, Knowlhill, Milton Keynes, MK5 8NL, UK Telephone +44 (0)1908 857 750 Email: acsl@intertek.com



PRODUCT SCHEDULE FOR CERTIFICATE 150 B CE HENRY SCHEIN INC

Intertek

DEVICE LISTING

Sutures Dental Alloys HS Ionospehere HS Stratosphere HS Troposhere Medicated Gelatine Sponges Rapid Cold Pack Surgical Scalpel Blades and disposable scalpels Disposable safety lancets

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