EC Certification



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.

EBIOX LTD

822 Fountain Court, Birchwood Boulevard, Birchwood, Warrington WA3 7QZ

Trionic D and Solo disinfecting products – wipes, sprays and concentrate for use on non invasive medical devices - see attached schedule

Certificate Number: Initial Certification Date: Certificate Effective Date: Certificate Expiry Date: 247-01 B CE 08 February 2006 08 February 2016 07 August 2016

Intertek Intertek Intertel

Brian Johnson

AMTAC Certification Services Limited, Milton Keynes, UK This certificate is the property of AMTAC Certification Services 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.

PRODUCT SCHEDULE FOR CERTIFICATE 247-01 B CE EBIOX LTD

Intertek

Trionic Trionic spray Trionic wipes SOLO disinfectant wipes SOLO disinfectant spray SOLO concentrated disinfectant cleaner Liquid disinfectant concentrate Disinfectant spray Disinfectant wipes Disinfectant wipes Disinfectant spray Liquid disinfectant concentrate

Initial Certification Date: 08 February 2006 Certificate Effective Date: 08 February 2016

Brian Johnson ~ Authorized Signatory