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 - restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions - 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.

DTR MEDICAL LIMITED

17 Clarion Court, Clarion Close, Swansea Enterprise Park, Swansea SA6 8RF

Sterile ear specula, Sterile tongue depressors, Sterile nasal specula, Sterile dental, laryngeal and nasal mirrors, Sterile suture and dissection forceps, needle holders, packing forceps, scalpel blade handles and clamp covers), Sterile ENT hooks and probes, Sterile dental syringes
Sterile gynaecological instruments (comprising endocervical specula, uterine polyp forceps, vulsellum forceps and probes), Sterile vaginal specula (including insulated and non-insulated specula and specula with smoke evacuation), Sterile stoma bridges, Sterile myringotome blade handles, Sterile cream applicators, Sterile tube adaptors, Sterile cottons buds, Sterile nasal gate clamps, Sterile tympanoplasty moulds

Certificate Number: **601 C CE**
Initial Certification Date: **12 March 2014**
Certificate Effective Date: **12 March 2014**
Certificate Expiry Date: **11 March 2019**

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 certificate.validation@intertek.com 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.

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