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
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