

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 688799**

Issued To:


**DTR Medical Ltd
17 Clarion Court
Clarion Close
Swansea
SA6 8RF
United Kingdom**

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Albert Roossien, Regulatory Lead

First Issued: **2019-02-14**Date: **2019-02-28**Expiry Date: **2020-10-18****...making excellence a habit.™**

Page 1 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Certificate No: CE 688799

Certificate Scope:

Manufacture and final inspection of:**Aspirating needles, aspirating cannula and flushing needles****Single-use surgical instruments (comprising forceps, scissors, biopsy punches, rongeurs, retractors, aspirating dissectors, curettes, hooks, probes and points)****Minor procedure packs (including myringotomy packs, ENT packs, suture packs, delivery packs and neuro-burr trays)****Tracheal dilators****Arterial cannula****Gigli saw blades****Suction handles, micro-suction handles, micro-suction devices, Zoellner fine ends, suction regulators, spigots and silicone suction tubing****Silicone bands and silicone slings****Single-use insufflation cannula****Aspects of manufacture concerned with securing and maintaining sterility relating to:****Ear, nose and eye specula, tongue depressors, dental, laryngeal and nasal mirrors, suture and dissection forceps, needle holders, packing forceps, scalpel blade handles and clamp covers, ENT hooks and probes, dental syringes, gynaecological instruments (comprising endocervical specula, uterine polyp forceps, vulsellum forceps and probes), vaginal specula (including insulated and non-insulated specula and specula with smoke evacuation), rectal specula, myringotome blade handles, cream applicators, nasal gate clamps, tympanoplasty moulds.**First Issued: **2019-02-14**Date: **2019-02-28**Expiry Date: **2020-10-18**

...making excellence a habit.™

Page 2 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.