By Royal Charter

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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-02-14** Date: **2020-08-14** Expiry Date: **2024-05-26**

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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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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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.

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Supplementary Information to CE 688799

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NBOG code(s)	Device description	Intended purpose
Class IIa		
MD0102 MDS7006	Aspirating needles, aspirating cannula and flushing needles Arterial cannula	Not applicable for class IIa devices
	Single-use insufflation cannula	
MD0106 MDS7006	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	
	Gigli saw blades & handles	
	Suction handles, micro-suction handles, micro-suction devices, Zoellner fine ends, suction regulators, spigots and silicone suction tubing	
	Silicone bands and silicone slings	

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NBOG code(s)	Device description	Intended purpose
Class Is		
MD 0106 MDS 7006	Ear, nose and eye specula	Not applicable for Class Is devices
	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), and rectal specula	
	Myringotome blade handles	
	Cream applicators	

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NBOG code(s)	Device description	Intended purpose
Class Is		
MD 0106 MDS 7006	Nasal gate clamps	Not applicable for class Is devices
	Tympanoplasty moulds	

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