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: **2021-04-20** Expiry Date: **2024-05-26**

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By Royal Charter

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 and Gigli saw blade handles.

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Supplementary Information to CE 688799

Issued To:

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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	
	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	
	Gigli saw blade handles	

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 688799**
Date: **2021-04-20**
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Date	Reference Number	Action
14 February 2019	8891403	First issue, Transfer from another Notified Body.
28 February 2019	8958424	Traceable to NB 0086.
14 August 2020	3095905	Certificate renewal Update to NBOG codes in supplementary information table
10 December 2020	3339181	Addition of EU Authorised Representative: Emergo Europe
20 April 2021	3410165	Removal of critical subcontractor Abarut Industries Addition of critical subcontractor Synergy Health Sterilisation (Swindon) Scope change and update to device tables – administrative change for Gigli saw blade handles as separate device
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
04 August 2022	3717908	Scope reduction: removal of minor procedure packs and tympanoplasty moulds Removal of critical subcontractors: Formagrind, PK Engineering, P W Coole & Son, Wall Colmonoy
26 April 2023	3912363	Addition of crucial supplier, Update to EU representative address, Administrative change to LM address

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Date	Reference Number	Action
08 May 2024	30169746	Addition of critical subcontractor for manufacture Removal of critical subcontractor for manufacture

Inspiring trust for a more resilient world.

08 May 2024

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

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 688799	93/42/EEC Annex V	30169746	Addition of critical subcontractor for manufacture Removal of critical subcontractor for manufacture

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices