

# UKCA Certificate - Production Quality Assurance

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

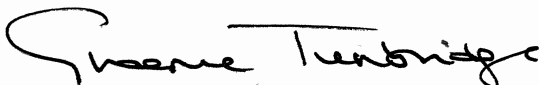
**No.** UKCA 780199  
**Issued To:** DTR Medical Ltd  
17 Clarion Court  
Clarion Court Enterprise Park  
Swansea  
SA6 8RF  
United Kingdom

In respect of:

**Manufacture and final inspection of sterile aspirating and flushing cannulae, suction devices, forceps, scissors, cervical biopsy punches, hooks and points, silicone bands and clamp covers, rongeurs, curettes and dissectors**  
**Those aspects of aspects of Annex V relating to securing and maintaining sterility of: nasal specula, silicone tubes, gynaecological instruments (Spackman cannula & vaginal specula), ear specula, probes, dental syringes, tongue depressors and clamps, sponge and needle holders.**

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex V [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class IIb and class III products an Annex III certificate (modified as described above) is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2023-03-10**

Date: **2023-03-10**

Expiry Date: **2025-08-14**

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## Supplementary Information to UKCA 780199

Issued To:

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**United Kingdom**

Device code	Device name	Intended purpose per IFU
<b>Class IIa</b>		
MD0102	Aspirating and flushing cannulae	---
	Suction devices	---
MD0106	Forceps	---
	Scissors	---
	Cervical biopsy punches	---
	Hooks and points	---
	Silicone band and clamp cover	---
	Rongeurs	---
	Curettes	---
	Dissectors	---
<b>Class Is</b>		
MD0102	Silicone tubes	---
MD0106	Nasal specula	---
	Gynaecological instruments	---
	Ear specula	---
	Probes	---
	Dental syringes	---
	Tongue depressors	---
	Clamps, sponge and needle holders	---

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## Certificate History

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Date	Reference Number	Action
Current	3786028	Issued; traceable to CE 688799

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