

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

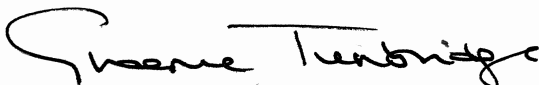
In respect of:

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 Annex V relating to securing and maintaining sterility of: nasal specula, silicone tubes, gynecological 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: **2024-01-23**

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

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

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

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000

Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.

A member of BSI Group of Companies.

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Supplementary Information to UKCA 780199

Issued To:

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Device code	Device name	Intended purpose per IFU
Class IIa		
MD0102	Aspirating and flushing cannulae	---
	Suction devices	---
MD0106	Forceps	---
	Scissors	---
	Cervical biopsy punches	---
	Hooks and points	---
	Silicone band and clamp cover	---
	Rongeurs	---
	Curettes	---
Dissectors	---	

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Device code	Device name	Intended purpose per IFU
Class Is		
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
2023-03-10	3786028	Issued; traceable to CE 688799
2023-04-26	3912362	Addition of crucial supplier
Current	30091598	Addition of a critical subcontractor for manufacture

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