

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 780152 R000

Manufacturer: DTR Medical Ltd

Address:

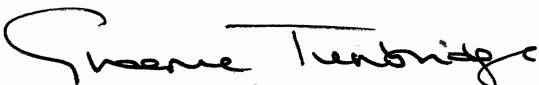
17 Clarion Court
Clarion Court Enterprise Park
Swansea
SA6 8RF
United Kingdom

Single Registration Number: GB-MF-000023112

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

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



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-03-14**

Current Issue Date: **2024-12-12**

Starting Validity Date: **2024-12-12**

Expiry Date: **2029-03-13**

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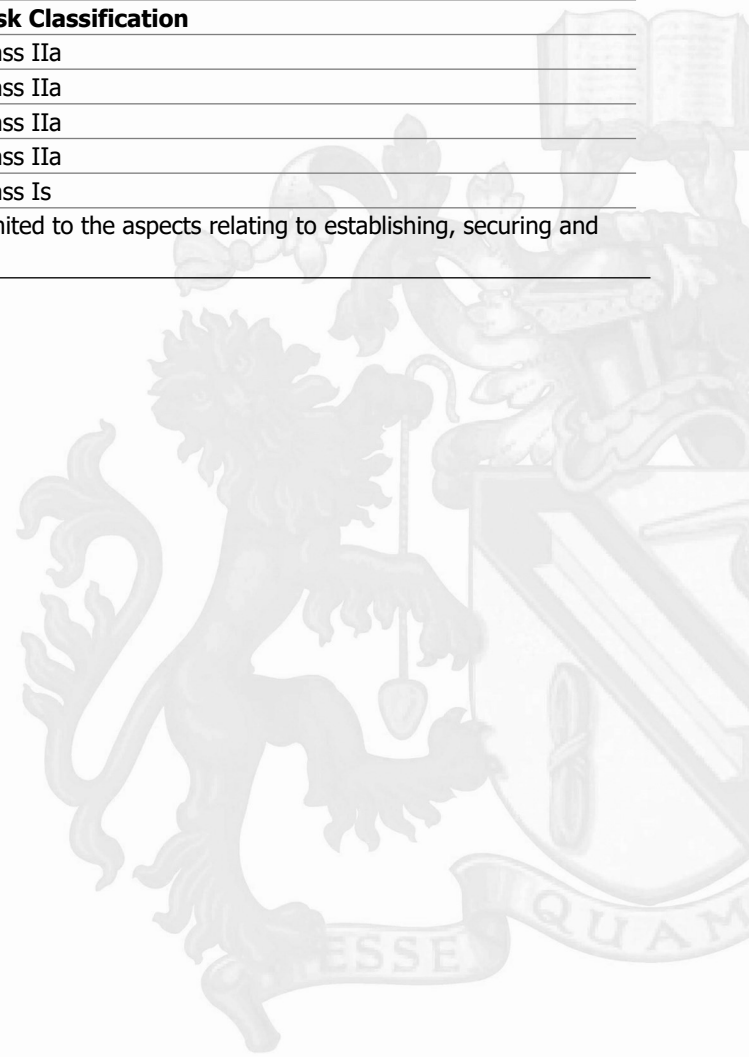
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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Surgical drainage systems	Class IIa
Forceps – ENT, suture and dissecting, arterial	Class IIa
Oral biopsy forceps / oral rotating biopsy punch	Class IIa
Cervical biopsy punch	Class IIa
Gynaecological devices	Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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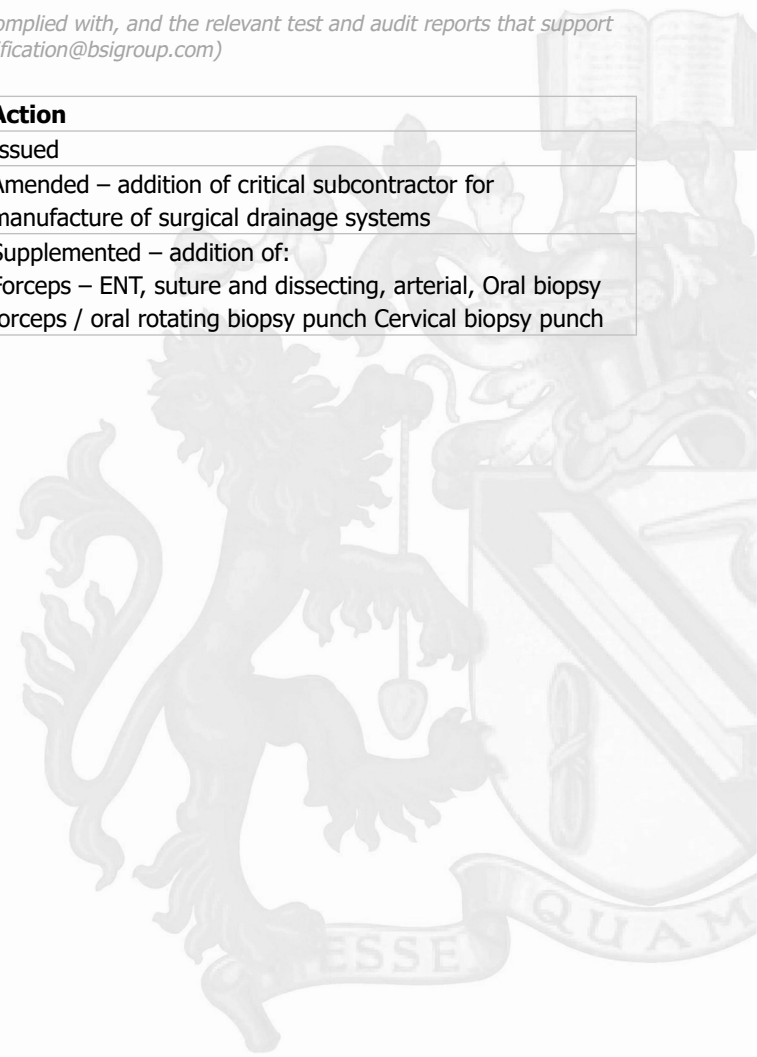
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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2024-03-14	3785743	Issued
2024-04-09	30159159	Amended – addition of critical subcontractor for manufacture of surgical drainage systems
Current	30245831	Supplemented – addition of: Forceps – ENT, suture and dissecting, arterial, Oral biopsy forceps / oral rotating biopsy punch Cervical biopsy punch



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