



NSAI

EU Quality Management System Certificate Medical Device Regulation 2017/745

The National Standards Authority of Ireland (NSAI) as a duly designated Notified Body, (identification number 0050) for the purposes of the European Union under MDR 2017/745

APPROVES THE QUALITY MANAGEMENT SYSTEM APPLIED BY

Class Medical Ltd

**Unit 1D
Annacotty Business Park
Annacotty
Co Limerick
Ireland**

Device Group: Transurethral Catheter Safety Valve (Class Medical TUC Safety Valve) – Adult type

Risk Class: Class 1 sterile

Conclusion: Quality Management System complies with the requirements of Annex IX, Chapter I & III of MDR 2017/745. The use of the NSAI Notified Body Identification Number 0050 in conjunction with CE Marking of Conformance for this product is hereby authorised.

Product Certificate Number:	745.003	Re-Issued Date:	Not applicable
First Issue Date:	17 February 2021	Expiry Date:	16 February 2026
Site Certificate Number:	MD19.8226		

Signed:

Approved by:
Dr Caroline Dore Geraghty
Head of Notified Body

Approved by:
Dr Elaine Darcy
European Medical Device Operations Manager

CONDITIONS FOR OR LIMITATIONS OF THE VALIDITY: this certificate remains valid on condition that the Approved Quality Management System is maintained in an adequate and efficacious manner in line with the requirements of the Regulation. This certificate is based on examination of identified relevant CS, harmonised standards, test reports and audit reports maintained on file with NSAI. The audit performed by NSAI was limited to the aspects required under Article 52(7). Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI. This certificate is limited to the sterile, measuring or reusable aspect of the device. Substantial Changes to the QMS or the product range covered must receive further approval from NSAI.

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

