



**17 February 2021**

Mr Raymond McEvoy  
Class Medical Ltd.  
Unit 1d, Annacotty Business Park  
Annacotty, Co Limerick  
Ireland

**RE: Transurethral Catheter Safety Valve (Class Medical TUC Safety Valve) – Adult type**

Dear Mr McEvoy

Further to your application for the product family above, I am pleased to inform you that your application under MDR 2017/745 has been approved as of **17 February 2021**.

Models: 0301 80000

Intended use: The TUC Safety Valve is indicated for single use during inflation of a Foley catheter retaining balloon, to prevent accidental inflation of the balloon in the urethra.

Indications for Use: Adult type TUC Safety Valve is not intended for patients aged under 16 years of age

Shelf life: 1 Year

Approval conditions: None

Our file reference for this Device Group is 745.003. Please quote this reference in all future correspondence.

The NSAI Notified Body number, 0050, may be used on the model(s) / trade name(s) listed above in conjunction with the CE Marking of conformance.

If you require any further copies of your certificate, please contact Gwen Thornberry at [gwen.thornberry@nsai.ie](mailto:gwen.thornberry@nsai.ie)

Yours Sincerely

A handwritten signature in black ink that reads "Elaine Darcy".

Elaine Darcy  
European Medical Device Operations Manager  
Medical Devices  
NSAI

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