



# Polish Centre for Testing and Certification

BM.433.0121.2021.0967.22.JJ

Warsaw, 27.05.2022

**Hangzhou Singclean Medical Products Co., Ltd.**  
**No.125 (E), 10th Street,**  
**Hangzhou Qiantang New area,**  
**Zhejiang310018, China**

Pursuant the application for change dated 29.04.2022 Polish Centre for Testing and Certification kindly inform that the review of changes to the Hangzhou Singclean Medical Products Co., Ltd. product has been accomplished. Provided documents indicate this change is acceptable and there is no adverse impact to the assays and their performance. On the basis of the documents provided and accelerated stability study, the change in the shelf life was accepted from 1 year to 24 months. Please remember that further stability studies are performed as planned and the results are submitted to the PCBC.

The change has been approved, revision of current EC certificate is not required.

Yours Sincerely,

Director  
Medical Device Certification Department

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