

BM.433.0121.2021/KW/MV/2024/0229

Warsaw, 16.04.2024

To Whom It May Concern,

Polish Centre for Testing and Certification informs about the change introduced to the EC Certificate No. **1434-IVDD-459/2021** issued for Hangzhou Singclean Medical Products Co., Ltd., which results from the five-year certification period in accordance with Art. 9 section 10 of the Directive 98/79/EC, in force at the time the certificate was issued.

The EC Certificate validity date has been updated to September 21st, 2026.

Implementation of the change does not represent a significant change in design or intended purpose under Regulation (EU) 2017/746 Article 110(3) and the related IVDD Certificate No. 1434-IVDD-459/2021 issued September 22nd, 2021 remains valid until its expiry date or May 26th, 2025, whichever comes first.

Yours Sincerely,

Head of Medical Device Certification Department