



POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

BM.433.0218.2021.KW.MV.2024.0184

Warsaw, 22.03.2024

To Whom It May Concern,

Polish Centre for Testing and Certification informs about the change introduced to the EC Certificate no. **1434-IVDD-460/2021** issued for Safecare Biotech (Hangzhou) Co., Ltd, 311121 Hangzhou, Building 2/203, No. 18 Haishu Rd.Cangqian Subdistrict, Yuhang District, China, 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 **22 September 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-460/2021 issued 23 September 2021 remains valid until its expiry date or 26 May 2025, whichever comes first.

Yours Sincerely,

**Head of Medical Device
Certification Department**



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Initial capital
16.000.000 PLN
(fully paid)

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The company registered in the District Court for
the Capital City of Warsaw, XIIIth Commercial Division