

POLISH CENTRE FOR
TESTING AND CERTIFICATION

No. 1434-MDR-024/2024

**of Conformity of the Quality Management System EU with the requirements
of Chapters I and III of the Annex IX to the Regulation (EU) 2017/745
issued to manufacturer:**

Aflofarm Farmacja Polska Sp. z o.o.
ul. Partyzancka 133/151, 95-200 Pabianice
Single Registration Number (SRN): PL-MF-000001809

Polish Centre for Testing and Certification S.A. (Notified Body no. 1434) certifies that the manufacturer has established, documented and implemented a Quality Management System as described in article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details of the devices covered by this certificate are described on the following pages. The Report referenced below summarizes the result of the assessment and includes reference to the relevant common specifications, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapters I and III to the regulation mentioned above. The quality management system assessment was accompanied by the assessment of technical documentation completed with the issuance of the EU technical documentation assessment certificate. The certified Quality Management System is subject to periodical surveillance by PCBC S.A.

Report no.: **S/703/BM/2022**

Validity of the Certificate: from 12.12.2024 to 11.12.2029

The date of issue of the Certificate: 12.12.2024

Certificate bears the qualified signature PCBC S.A.
Warsaw, 12/12/2024

FBM-R-27-MDR-E/2 of 27.09.2024

Polish Centre for Testing and Certification

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CERTIFICATE