Medinice S.A.
Ul. Stefana Hankiewicza 2
02-103 Warsaw

13 FEBRUARY 2026

CURRENT REPORT NO. 5/2026
DATED 13 FEBRUARY 2026

Title: Receipt of FDA clearance under the 510(k) premarket notification pathway, permitting the CoolCryo device to be legally marketed in the United States.

Legal basis: Article 17(1) of Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (MAR) – inside information.

The Management Board of Medinice S.A. (the "**Company**"), with reference to current reports No. 14/2025 and 2/2026, informs that on 13.02.2026 the Company received from the U.S. Food and Drug Administration ("FDA") clearance under the 510(k) procedure confirming the substantial equivalence of the CoolCryo medical device to a predicate device. Receipt of the clearance means the right to place CoolCryo on the market in the United States.

The Management Board of the Company indicates that obtaining FDA clearance constitutes a significant milestone in the implementation of Medinice S.A.'s development strategy in the scope of commercialization of the CoolCryo project on the U.S. market. The Company will inform about further significant events related to the implementation and development of the project in the form of relevant current reports.

CoolCryo is a medical device intended for the treatment of cardiac arrhythmia by performing cardiac surgical cryoablation.