Medinice S.A.
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16 January 2026

CURRENT REPORT NO. 2 / 2026
DATED 16 JANUARY 2026

Title: Submission of a formal response to the FDA regarding clearance of the CoolCryo device under the 510(k) pathway

Legal basis: Article 17 section 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 report No. 14/2025 concerning the submission of an application to the U.S. Food and Drug Administration ("FDA") for clearance of the CoolCryo device under the 510(k) pathway, hereby announces that on 16 January 2026 the Company submitted a formal response to the FDA's request for additional information ("additional information request"), received in the course of the 510(k) procedure.

The submission of the above response constitutes the completion of the stage of assessment of equivalence of the CoolCryo device in relation to a reference device approved on the U.S. market (the predicate device) and initiates the final stage of the FDA's decision-making process, which, in accordance with the applicable procedures, lasts 30 calendar days. After this period, the FDA will inform the Company whether the CoolCryo device has been recognized as equivalent to the reference device.

The Management Board considers this information to be material for the implementation of the Company's development strategy and for the possibility of commercialization of the project and its implementation on the market in the United States. The Company will promptly inform about any material decisions of the FDA in the form of current reports.

CoolCryo is a medical device intended for the treatment of arrhythmias through the performance of cardiac surgical cryoablation of the heart. It is anticipated that, due to its unprecedented freezing power, the CoolCryo device may potentially shorten the duration of cardiac surgical procedures and open new possibilities for the surgical treatment of arrhythmias.