NORMATIVE INSTRUCTION ANVISA No. 426, OF FEBRUARY 13, 2026

Establishes the requirements for the transmission and management of the database on Unique Device Identification UDI in compliance with RDC No. 591/2021.

CHAPTER I – PRELIMINARY PROVISIONS

Art. 1 This Normative Instruction establishes the requirements for the transmission and management of the data that compose the UDI database in Brazil, within the scope of activities related to the UDI System for medical devices, pursuant to RDC No. 591/2021.

Art. 2 Definitions:

I – Unique Device Identification System SIUD: Brazil's UDI database.

II – UDI data: dataset characterizing a medical device model associated with its UDI-DI.

III – Sanitary regularization: authorization granted by ANVISA allowing lawful commercialization.

IV – Placement on the Brazilian market: commercialization by the registration holder.

CHAPTER II – DATA TRANSMISSION

Art. 3 Devices must have UDI data transmitted to SIUD before being placed on the Brazilian market.

Only the UDI-DI must be submitted. The UDI-PI must be maintained internally for traceability.

Art. 4 Transmission may be individual or in bulk, following SIUD implementation guidelines.

Art. 5 Each UDI dataset corresponds to one UDI-DI and one device model.

Art. 6 Data will be published once the informed publication date is reached.

Corrections:

Art. 7 Corrections are permitted within 60 calendar days after publication.

Changes requiring a new UDI-DI must be processed within 30 days.

Art. 8 Ownership transfers must follow RDC No. 903/2024 before SIUD updates.

Art. 9 UDI-DI must be inactivated within 30 days in cases of discontinuation, expiration, or cancellation.

CHAPTER III – THIRD-PARTY USERS

Art. 10 The registration holder is responsible for UDI transmission and may authorize third parties.

CHAPTER IV – DEADLINES

Art. 11 Mandatory deadlines follow RDC No. 591/2021 by risk class. Voluntary submissions are allowed before mandatory dates.

CHAPTER V – FINAL PROVISIONS

Art. 12 Previously marketed devices may be voluntarily submitted.

Art. 13 ANVISA may suspend transmissions to preserve system operation.

Art. 14 ANVISA will publish implementation guidance.

Art. 15 Noncompliance constitutes a sanitary violation under Law No. 6,437/1977.

Art. 16 This Normative Instruction enters into force on March 1, 2026.

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