

Ministry of Health – MS

National Health Surveillance Agency - ANVISA DRAFT

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

Establishes the requirements for the submission and management of the Unique Device Identification (UDI) database in compliance with Collegiate Board Resolution – RDC No. 591, of December 21, 2021.

THE COLLEGIATE BOARD OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, in the exercise of the powers conferred upon it by Articles 7, item III, and 15, items III and IV, of Law No. 9,782, of January 26, 1999, and considering the provisions of Article 187, item VII and §1, of the Internal Regulations, approved by Collegiate Board Resolution – RDC No. 585, of December 10, 2021, resolves to adopt the following Normative Instruction, as deliberated at the meeting held on January 28, 2026, and I, the Chief Executive Officer, hereby determine its publication:

CHAPTER I

PRELIMINARY PROVISIONS

Art. 1º This Normative Instruction establishes the requirements for the submission and management of the data comprising the UDI database in Brazil, within the scope of activities related to the UDI System for medical devices, pursuant to §3 of Article 15 of ANVISA RDC Resolution No. 591, of December 21, 2021, which provides for the identification of medical devices regulated by ANVISA through the Unique Device Identification (UDI) System, or any regulation that may replace it.

Sole paragraph. This Normative Instruction applies to all medical devices falling within the scope of ANVISA RDC Resolution No. 591/2021 or any regulation that may replace it.

Art. 2º For the purposes of this Normative Instruction, the definitions set forth in ANVISA RDC Resolution No. 591/2021, or any regulation that may replace it, shall apply, in addition to the following definitions:

I – Unique Device Identification System (SIUD): the name of the Brazilian UDI database, an electronic system containing the information and other identification elements associated with a given medical device;

II – UDI data: the dataset characterizing a medical device model, associated with and identified by its UDI-DI;

III – regulatory authorization: authorization allowing a medical device to be lawfully manufactured, imported, advertised, distributed, marketed, dispensed, and used, through notification or marketing authorization (registration), issued by ANVISA; and

IV – making available on the Brazilian market: commercialization in Brazil by the company holding the regulatory authorization.

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CHAPTER II

DATA SUBMISSION

Section I

Initial Submission

Art. 3º Medical devices falling within the scope of ANVISA RDC Resolution No. 591/2021, or any regulation that may replace it, prior to being made available on the Brazilian market and without prejudice to other applicable regulatory obligations, shall have their UDI data submitted to the SIUD.

§1. The submitted UDI data shall be equivalent to the medical device data approved by ANVISA, and it is the responsibility of the marketing authorization holder to ensure such equivalence.

§2. Only the UDI-DI component of the UDI code shall be provided in the UDI dataset to be submitted.

§3. The requirement to submit only the UDI-DI component does not exempt the obligation to maintain the UDI-PI component within the company's Quality Management System, in order to ensure full traceability of the device, under the terms of ANVISA RDC Resolution No. 665, of March 30, 2022, or any regulation that may replace it.

Art. 4º The submission of UDI data may be:

I – individual, when a single UDI dataset is submitted for one medical device model at a time, by completing a specific electronic form within a user-friendly interface in the SIUD; or

II – in bulk, when one or more UDI datasets are submitted simultaneously for one or more medical device models through submission of a previously structured file prepared under the responsibility of the marketing authorization holder, in accordance with SIUD documentation, whether by manual file upload through a user-friendly interface or by machine-to-machine communication through the designated SIUD channels.

Sole paragraph. It is the responsibility of the company holding the sanitary registration to implement the application or other mechanism that allows it to carry out mass transmission, should it wish to use this type of transmission, and to do so, it must follow the requirements provided in the implementation guide indicated on the Anvisa electronic portal.

Art. 5º Each submitted UDI dataset shall correspond to a single UDI-DI code, referring to one model of a medical device.

Sole paragraph. Only the marketing authorization holder at ANVISA, or a third-party user authorized by it through SIUD, may submit UDI data for a given medical device.

Art. 6º UDI data submitted to the SIUD shall be published once the publication date indicated at the time of submission is reached and shall thereafter be made available for consultation on ANVISA's official website.

Section II

Corrections to Submitted Data

Art. 7º Corrections to UDI data shall be permitted during a grace period of 60 consecutive calendar days from the date of publication of the UDI data.

§1. After expiration of the grace period, only data elements that do not require issuance of a new UDI-DI may be modified, as provided in Annex II of ANVISA RDC Resolution No. 591/2021, or any regulation that may replace it.

§2. The publication date, once reached, may not be modified.

§3. If modification of any data element requiring issuance of a new UDI-DI is necessary, as defined in item 2.9 of Annex I, Section II of ANVISA RDC Resolution No. 591/2021, or any regulation that may replace it, the UDI-DI replacement operation shall be performed in the SIUD within 30 consecutive calendar days from the date of publication of such amendment in the Official Gazette of the Union (DOU).

Art. 8º In cases of transfer of ownership of the marketing authorization of a medical device, the formal procedures for transfer of ownership, pursuant to ANVISA RDC Resolution No. 903, of September 6, 2024, or any regulation that may replace it, shall be completed prior to performing any operation in the SIUD.

Sole paragraph. Following completion of the ownership transfer process, the successor company shall submit the UDI-DI data associated with the new marketing authorization numbers within 30 days after the effective date of the specific Resolutions concerning cancellation and transfer of ownership of the registration.

Art. 9º The marketing authorization holder shall record in the SIUD, within 30 days, the discontinuation date for inactivation of the UDI-DI associated with medical devices that have:

I – the availability of the product in the Brazilian market has been discontinued by the company holding the sanitary registration for the product

II – expiration of the regulatory authorization; or

III – cancellation of the regulatory authorization.

§1. In the case referred to in item III, the time period shall be counted from the first business day following the date of publication of the act cancelling the regulatory authorization in the Official Gazette of the Union (DOU).

§2. Inactivation of the UDI-DI in the SIUD does not affect the use, commercialization, or donation of used medical devices permitted under the terms of ANVISA RDC Resolution No. 579, of November 25, 2021, or any regulation that may replace it.

CHAPTER III

REGISTRATION OF THIRD-PARTY USERS

Art. 10º It is the responsibility of the company holding the sanitary registration for the medical device with Anvisa to transmit the UDI data for its products.

§1. The marketing authorization holder may register third-party users through the SIUD to submit UDI data on its behalf.

§2. The registration and management of third-party users are the responsibility of the marketing authorization holder, which shall define the scope of products for which the registered third-party user is authorized to submit UDI data.

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CHAPTER IV

DEADLINES FOR COMMENCEMENT OF SUBMISSIONS

Art. 11º After the effective date of this Normative Instruction, the deadlines for mandatory submission of UDI data for medical devices to be made available on the market shall be those established in Article 15 of ANVISA RDC Resolution No. 591/2021, or any regulation that may replace it, as provided in §3 of the aforementioned Article.

Sole paragraph. Until the mandatory compliance date specified according to the risk class of the medical device is reached, UDI data may be submitted to the SIUD on a voluntary basis.

CHAPTER V

FINAL AND TRANSITIONAL PROVISIONS

Art. 12º Medical devices have already been commercialized and still in use on the date this Normative Instruction enters into force may have their UDI data submitted on a voluntary basis at any time.

Art. 13º ANVISA may, at any time and for an indefinite period, suspend the submission of UDI data for specific types of medical devices.

§1. The suspension referred to in the caput may only be applied to preserve the operational viability of the SIUD, considering the available technological and infrastructure limitations.

§2. In the event such suspension is applied, the measure shall be formalized by publication on the Agency's official website.

Art. 14º ANVISA shall publish on its official website a manual with guidance for the use of the SIUD and an implementation guide for the adopted data structuring and transmission standard.

Art. 15º Failure to comply with the provisions set forth in this Normative Instruction constitutes a sanitary violation under Law No. 6,437, of August 20, 1977, without prejudice to applicable civil, administrative, and criminal liabilities.

Art. 16º This Normative Instruction shall enter into force on March 1, 2026.

LEANDRO PINHEIRO SAFATLE

President - Director

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