MAN_09 - UDI compliance requirements for *in vitro* diagnostic (IVD) devices: Labeling implications for Bio-Manguinhos/Fiocruz

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Introduction: A Unique Device Identification (UDI) system is intended to provide a positive and globally harmonized identification of medical devices by requiring them to contain a unique identifier at the label. It has the Device Identifier (DI), which is a fixed sequence that identifies the device manufacturer as well as the specific model or version, and the Production Identifier (PI) that refer to batch or serial number, specific date of manufacture or expiration date. As Brazil is a founding member of International Medical Device Regulators Forum (IMDRF), Anvisa has established and rolled out its proposed framework for UDI requirements through RDC 591/2021. The manufacturer's quality management system shall implement control mechanisms that guarantee the correct assignment of the UDI to all devices manufactured by him or on his behalf. This process will be implemented for all diagnostic products regulated by Anvisa at Bio-Manguinhos, requiring a review of packaging materials.

Objectives: Provide a Specific Roadmap to verify and fulfill obligations of the UDI implementation, along with the compliance dates established by Anvisa and labeling implications for Bio-Manguinhos's products.

Methodology: The first step was to verify and set apart the IVD products of Bio-Manguinhos in accordance with the risk class and quantity per package configuration. After these, it was necessary to contact GS1 to generate datamatrix and for production. Finally, it was established a change control process for UDI allocation schedule according to the risk and the impact of labeling alteration at Bio-Manguinhos.

Results: There are 43 IVD produced at Bio-Manguinhos that are regulated by Anvisa with the following deadline of UDI allocation on the labels: 11 class risk IV (July 4, 2024); 28 class risk III (January 4, 2025); 1 class II (January 4, 2026) and 2 class risk (January 4, 2028). After the meeting with GS1, it was done the GTIN/ENA registration and the update of the products with the National Product Registration (cnp.gs1br.org); After GS1 validation, it was established a change control to run the implementation, starting with the class risk IV.

Conclusion: The work allowed the awareness and dissemination of the UDI requirements and deadlines for IVD among the different areas involved in Bio-Manguinhos. Furthermore, it was verified that this alteration implies in a good distribution management, patient safety and has a minimum impact over the labeling since only 3 product labels are produced outside the Institute and it is easy to reconcile packaging material exhaust date, new label layout and on- time deliveries to Health Ministry.

Keywords: UDI; Requirements; IVD