

Labelling document

VR-CARDIO: stand-alone medical device software, Class IIb (MDR 2017/745)

Manufacturer: SpikaTech S.L. · SRN ES-MF-000044822 · Label code 001/01



Translation of the original Spanish document «Documento de etiquetado» (label code 001/01). In case of discrepancy, the Spanish version prevails.

1. How the labelling is presented

VR-CARDIO is a computer program that is a medical device in its own right (MDSW). It is distributed without a physical medium or packaging, so its label is **electronic** and is shown within the application itself.

The user opens the label from the application's start menu by pressing the «**Label**» button. The label is available at any time, before and after signing in.

In accordance with Regulation (EU) 2017/745, Annex VI, Part C, sections 6.5.4 and 6.5.6, the unique device identifier (UDI) is shown in **human-readable form (HRI)** on an easily accessible screen. The automatic identification and data capture format (AIDC) is not required on software screens, so the label carries no barcode or DataMatrix code.

2. Electronic label



VR-CARDIO
VRCardio-VHET360-Visualization · Versión 1.0.0

MD

Producto sanitario

UDI

(01)08437028381002(8012)1.0.0

REF

8437028381VR-CARDIOL4



SpikaTech S.L.
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2024-12-02

 **2803**  

Consulte las instrucciones de uso antes de utilizar el producto.
Este software ha sido diseñado para la visualización, el análisis y la interacción con procesos electrofisiológicos cardíacos.
Condiciones de uso: uso exclusivo por profesional médico autorizado.

Código de etiqueta / versión de etiqueta: 001/01

Figure 1. Content of the «Label» screen of VR-CARDIO v1.0.0

The label is displayed in Spanish, the label language. Translation of its texts:

Producto sanitario	Medical device
Versión	Version
Consulte las instrucciones de uso antes de utilizar el producto.	Consult the instructions for use before using the product.
Este software ha sido diseñado para la visualización, el análisis y la interacción con procesos electrofisiológicos cardíacos.	This software has been designed for the visualisation and analysis of, and interaction with, cardiac electrophysiological processes.
Condiciones de uso: uso exclusivo por profesional médico autorizado.	Conditions of use: for use only by an authorised medical professional.
Código de etiqueta / versión de etiqueta	Label code / label version

3. Product identification data

Trade name / model	VR-CARDIO
Product type	Stand-alone medical device software (MDSW)
Risk class	IIb (Regulation (EU) 2017/745)
Software version	1.0.0
Reference (REF)	8437028381VR-CARDIOL4
Basic UDI-DI	8437028381VR-CARDIOL4
UDI-DI (GTIN-14)	08437028381002
UDI-PI (software version, AI 8012)	1.0.0
Full UDI (HRI)	(01)08437028381002(8012)1.0.0
UDI issuing entity	GS1 (company prefix 8437028381, AECOC / GS1 Spain)
Manufacturer	SpikaTech S.L. (Tax ID CIF B87386900) C/ Alcalá de Guadaira, nº 6, 6ª Derecha, 28018 Madrid
Manufacturer SRN	ES-MF-000044822
Notified body	HTCert, No. 2803
Date of manufacture	2024-12-02
Label language	Spanish
Label code / version	001/01

4. Symbols used

Symbol	Meaning	Reference
	Medical device	ISO 15223-1:2021, 5.7.7
	Unique device identifier	ISO 15223-1:2021, 5.7.10
REF	Catalogue number	ISO 15223-1:2021, 5.1.6
	Manufacturer	ISO 15223-1:2021, 5.1.1
	Date of manufacture	ISO 15223-1:2021, 5.1.3
	CE marking with the notified body number	Regulation (EU) 2017/745, Art. 20 and Annex V
	Consult the instructions for use	ISO 7010, M002
	Caution	ISO 15223-1:2021, 5.4.4