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Title:	E03 Revi® Wearable Device Label for US Commercial Use			

Revision History

Revision	Description of Change	Revision By	Position	Date
01	Initial release	Mechanical R&D Engineer	Rotem Sokolovsky	Jun 2023
02	- Section 6.2- Color changed from Pantone 300C to Pantone 116-13C - Section 8.4.2, BLE FCC ID changed to align with the label file - Label picture changed: ○ R symbol was added. ○ BLE FCC ID changed	Mechanical R&D Engineer	Rotem Sokolovsky	January 2025

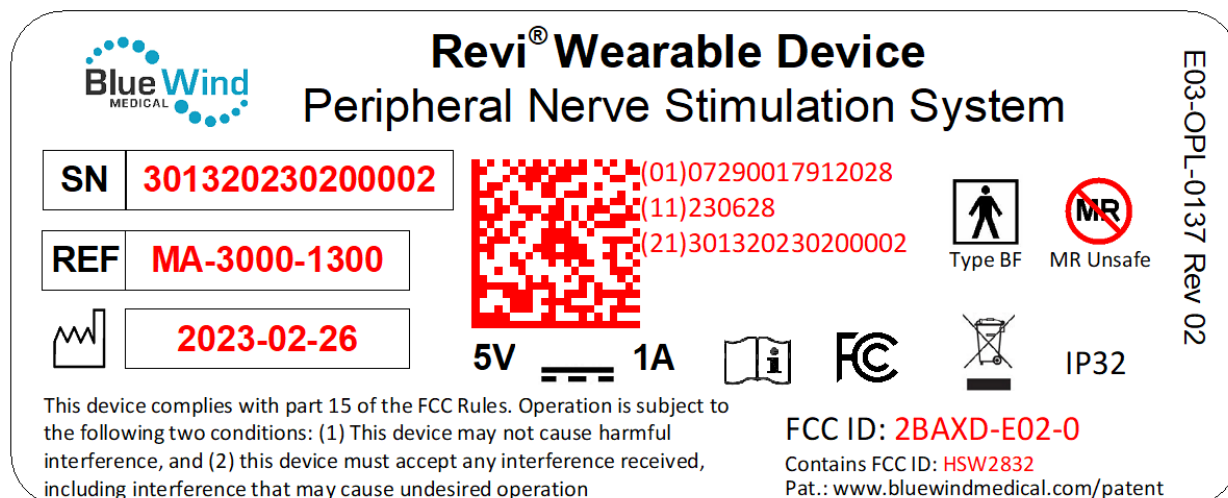
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1 Purpose

This document specifies the format of the E03 Revi® Wearable Device label.



Notes:

1. Tolerances for all dimensions (both in the notes and in the drawing), $\pm 0.5\text{mm}$.
2. Label revision: Rev02.
3. Label Size: Width: 74mm, Height: 28mm.
4. Material:
 - 4.1. Facestock- Gloss White coated polyester
 - 4.2. Adhesive- Permanent, Acrylic based.
5. FONT: All fonts are to be DIN NEXT LT PRO.
6. Color Print:
 - 6.1. Color 1- Red color, Pantone 2347C
 - 6.2. Color 2- Light blue color, Pantone 116-13C
7. Drawing not to scale
8. All text in red for illustration only and need to be changed according to the following:
 - 8.1. SN: to be assigned according to Appendix C, (3RR3YMMNNNNN)
 - 8.2. REF: according to the Master Assembly number (MA-3000-1300)
 - 8.3. Manufacture date: Indicates the date when the medical device was manufactured.
 - 8.4. FCC ID:
 - 8.4.1. FCC ID: 2BAXD-E02-0
 - 8.4.2. Contains FCC ID: HSW2832
 - 8.5. UDI: to be assigned According to Appendix A – C:
 - 8.5.1. (01)- 07290017912042
 - 8.5.2. (11)- Manufacture Date, YYMMDD.
 - 8.5.3. (21)- 3RR3YMMNNNNN

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2 Appendixes

Appendix A - The UDI Components according to GS1 Standards

UDI element		GS1 standard	Format
DI		(01) GTIN	14-digit format, see Appendix B
PI – GS1 Application Identifiers (AIs)	Batch/Lot number	(10)	20 alphanumeric characters
	Manufacturing date	(11)	YYMMDD
	Expiration date	(17)**	YYMMDD
	Serial Number	(21)	up to 20 alphanumeric characters, see Appendix C.
	Anode-cathode calibration factor	(240)**	up to 99 alphanumeric characters - First 20 digits of the calibration factor
	Cathode-anode calibration factor	(250)**	up to 99 alphanumeric characters- Second 20 digits of the calibration factor
ex: (01)07290016928006(11)141231(17)150707(10)A213B1(21)1234(xx)<specific data>			

*The list of individual UDIs for all components and packaging levels is described in the applicable WI, that are part of the DMR

**for implant only

Appendix B - (01) GTIN 14-digit format Assigning

NA	Israel PN by GS1			Company code (assigned by GS1)							item code		Check digit
0	7	2	9	0	0	1	7	9	1	2	A	B	C

Notes:

- Israel PN- permanent, assigned by GS1 for ISRAEL
- BWM Code-permanent, assigned by GS1 for Bluewind Medical
- Item code:
 - A- Identifies the packaging level. The field consists of a numeric value from 1 to 8. The number "0" is used in this position for the basic level of the device, and 1-8 for multiple unit packages.
 - B- Assigned by BWM for each product with SN. 1: implant, 2: G02 ECU, 3: CP, etc.
- Check Digit (C), use a calculator [Check Digit Calculator – GS1 US-](#)
 - Sum up the digits in the even positions of the GTIN 14 (from 7 to B) and multiply by 3.
 - Sum up the digits in the odd places.
 - Sum the result from 4.1 and 4.2
 - The check digit is complemented to the nearest (upper) multiple of 10.
 - Example:**
 - let A=0, B=4.
 - $(2+0+1+9+2+4) \times 3 = 54$.
 - $(7+9+0+7+1+0) = 24$.
 - $+24=78$.
 - 80 (nearest, upper, multiple of 10) – 78 = 2
 - Check digit= 2

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Appendix C - (21) E03 ECU Assigning Serial Number

ECU S/N according to the following table:

S/N	Number of Bits	Values Range	Elaboration	Example:
T	2	1-4	ECU Type: 1= AT-ECU 2= G02 ECU 3= E03 ECU	3 (E03 ECU)
RR	5	01-32	Hardware Revision ECU BOM AT- ECU PCBA BOM	01
Z	2	1-4	Subcontractor: 1-BWM 2- Sanmina 3- Plexus	3 (Plexus)
YY	5	17-48	Manufacture Year: 2017-2048	23
MM	4	01-12	Manufacture Month: Jan-Dec	02 (February)
NNNN	14	00001-16384	ECU Number in Batch	00001

Format S/N:	T	R	R	Z	Y	Y	M	M	N	N	N	N	N
Example S/N:	3	0	1	3	2	3	0	2	0	0	0	0	1

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