 <b>NEURO</b>	Document number <b>10216-01</b>	Rev <b>E</b>	<b>Sheet 1 of 2</b>
<b>PART SPECIFICATION</b>	Title <b>NIPG1000 IPG Kit Labeling on outer box &amp; pouch Artwork</b>		
<i>Confidential &amp; Proprietary</i>			

## 1. SCOPE


1.1. IPG Kit Labeling on outer box & pouch for “IPG Kit” (NIPG1000)

## 2. APPLICABLE DOCUMENTS

2.1. SOP08: Nevro Purchasing and Receiving Inspection document

## 3. REQUIREMENTS

3.1. Artwork:




# SENZA™ IPG Kit


## REF NIPG1000

**Contents:** One Implantable Pulse Generator, Accessories, Product Literature


**Recharge before implanting**

**STERILE** | **EO**








0°C  
32 °F



45°C  
113°F











**SN: PL100XXXX**

**LOT: X000**






**FCC ID: XKYIPG1000**




0086

**EC REP**  
MDSS GMBH  
Schiffgraben 41  
D-30175 Hannover,  
Germany



**CAUTION:**  
**Investigational  
Device Limited by  
Federal (USA) law to  
investigational use.**



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### 3.2. Functional Requirements

- 3.2.1. Label must stay adhered to the box under expected temperature and humidity conditions that can be encountered during transport and storage and indicated shelf life
- 3.2.2. Label must show all symbols and information shown in the artwork
- 3.2.3. Ink used on label must not rub off when using alcohol against ink

### 3.3. Visual Requirements

- 3.3.1. Label Background Color: White
- 3.3.2. Font Color: Black

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3.3.3. Font for Nevro: custom logo

3.3.4. Font for other text: Arial

#### 4. QUALITY SYSTEM

4.1. The supplier shall allow customer to perform pre-scheduled manufacturing facility audits, including review of applicable documentation.

#### 5. NOTIFICATION OF CHANGES

5.1. The supplier shall notify Nevro in writing prior to any change in the raw materials, process or place of manufacture. Nevro must approve all changes in writing before implementation.

#### REVISION HISTORY

Rev	DCN	Change Description	Release Date
A	00098	Initial release	02/09/2010
B	00297	Label updated to reflect CE Mark, Nevro's new address, inclusion of revision level, and translations of kit content	06/08/2010
C	00314	Label updated to reflect Nevro's correct address	06/14/10
D	00338	Revision level change to the label so as to be consistent with a change at the Pro Tech end to reflect a change in a variable field "Use Before Date", i.e. 12-month shelf-life instead of 6-months	08/02/10
E	00428	Removal of translated "Contents" verbiage from this label so that it can be accommodated on an additional label that will also be adhered to the box.	02/18/11