시점확인본
진본
2019-04-03
17:51:31
KST
청주시점확인센터

Document Number : OMAS-CSNM-QZMH-LP7T

Osong Health Technology Administration Complex,
187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu,
Cheongju-si, Chungcheongbuk-do, Korea, 28159
Tel: +82-43-719-3772, Fax: +82-43-719-3750

No. of Certificate : 20190048139

Date : 2019/04/03

Certificate of Free Sales

Exporting(certifying) country : Republic of Korea
Importing(requesting) country :

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following item(s) is(are) permitted to be freely sold in domestic and overseas markets.

Manufacturer (Registered No. : 1431)

LAXTHA Inc.

4F, 106, Techno 2-ro, Yuseong-gu, Daejeon

Product-License No.	Classification
16-4837	Electroencephalograph [2]

※Attached : List of Product Classification and Model

Jung, Jinee

Director of Medical Devices Policy Division
Department of Medical Device Safety Bureau
Ministry of Food and Drug Safety

This medical device is approved by National Institute of Medical Device Safety Information(NIDS) established under
Article 42 of Medical Device Act.

※ This certificate is issued on the Internet, you can check whether to forge or modify in homepage(emed.mfds.go.kr).
Furthermore, You can also check it by barcode exploiting document check program for scanner

Osong Health Technology Administration Complex,
187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu,
Cheongju-si, Chungcheongbuk-do, Korea, 28159
Tel: +82-43-719-3772, Fax: +82-43-719-3750

No. of Certificate : 20190048139 Date : 2019/04/03

Product License No. : 16-4837 (2018/06/11)

Classification : Electroencephalograph

Model(Export Name)

· neuroNicle FX2

※ Attached : Information Product and Model

식품의약품안전처

※ This certificate is issued on the Internet, you can check whether to forge or modify in homepage(emed.mfds.go.kr).
Furthermore, You can also check it by barcode exploiting document check program for scanner

Osong Health Technology Administration Complex,
187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu,
Cheongju-si, Chungcheongbuk-do, Korea, 28159
Tel: +82-43-719-3772, Fax: +82-43-719-3750

No. of Certificate : 20190048139

Date : 2019/04/03

Product License No. : **16-4837** **(2018/06/11)**

Manufacturer : **not applicable**

Legal manufacturer : **not applicable**

Combined medical device

- Electroencephalograph
- Sphygmograph
- Pulse rate meter

Composite medical device

- not applicable

※ Attached : Medical Device Accessaries

식품의약품안전처

※ This certificate is issued on the Internet, you can check whether to forge or modify in homepage(emed.mfds.go.kr).
Furthermore, You can also check it by barcode exploiting document check program for scanner

모양 및 구조 - 외형

[1] neuroNicle FX2

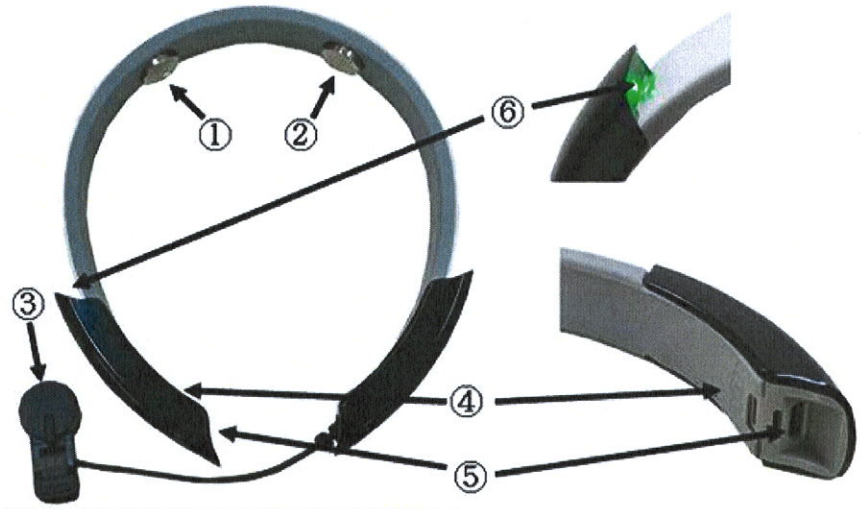
1. 외관사진

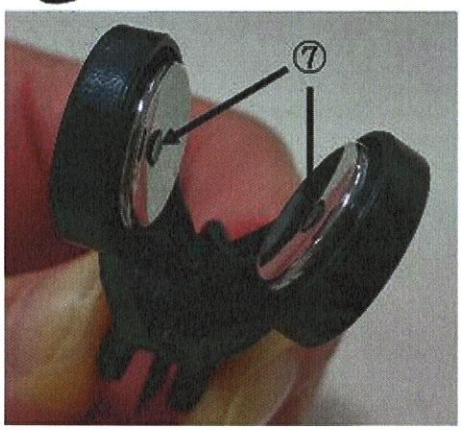


식품의약품안전처

※ This certificate is issued on the Internet, you can check whether to forge or modify in homepage(emed.mfds.go.kr).
Furthermore, You can also check it by barcode exploiting document check program for scanner

2. 외관설명



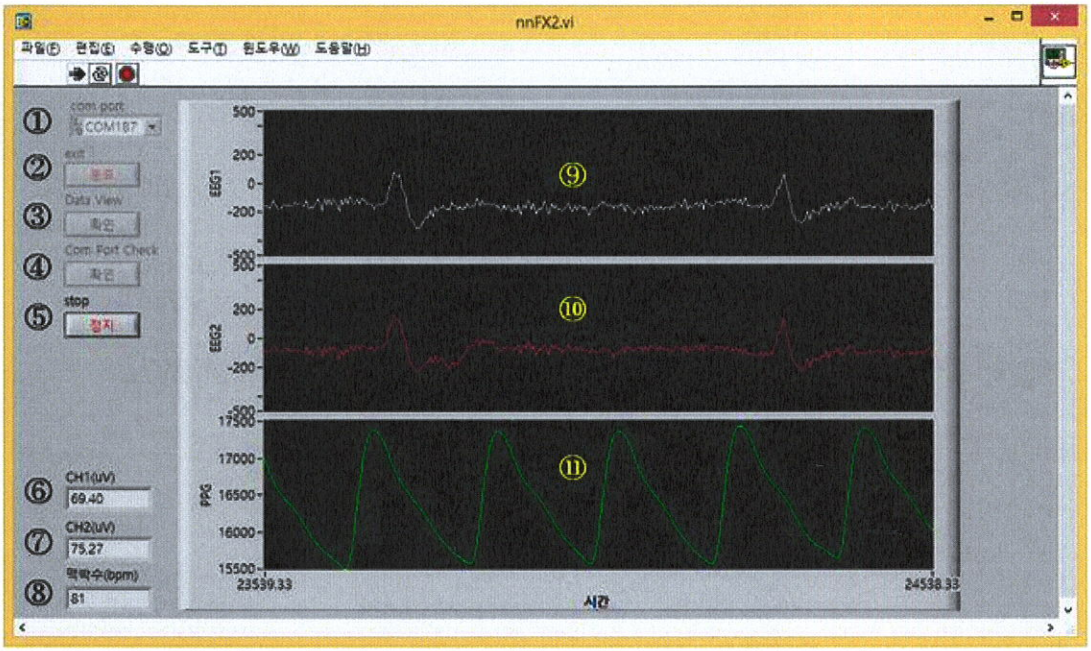


번호	명칭	설명
1	측정전극_CH1	Fp1(이마좌측)에 부착되는 CH1 전극
2	측정전극_CH2	Fp2(이마우측)에 부착되는 CH2 전극
3	기준/접지전극	우측 귓불에 부착되는 기준/접지전극
4	전원버튼	장치의 ON/OFF용 전원버튼
5	충전단자	충전용 USB 단자
6	LED	상태정보 제공용 LED
7	광센서	맥파 측정용 광센서

식품의약품안전처

※ This certificate is issued on the Internet, you can check whether to forge or modify in homepage(emed.mfds.go.kr).
Furthermore, You can also check it by barcode exploiting document check program for scanner

3. 소프트웨어 화면



일련번호	주요 기능	기능 설명
1	COM Port	COM port 목록을 나타낸다.
2	EXIT	COM port 연결해제
3	Data View	뇌파 모니터링 시작
4	Com Port Check	COM port 연결
5	Stop	파형 모니터링 정지
6	Ch1 진폭표시	Ch1 진폭표시
7	Ch2 진폭표시	Ch2 진폭표시
8	맥박수 표시	맥박수 표시
9	Ch1 파형	Ch1 뇌파파형을 표시한다.
10	Ch2 파형	Ch2 뇌파파형을 표시한다.
11	맥파 파형	맥파파형을 표시한다.

식품의약품안전처

※ This certificate is issued on the Internet, you can check whether to forge or modify in homepage(emed.mfds.go.kr).
Furthermore, You can also check it by barcode exploiting document check program for scanner

4. 구성품

4.1 충전용 micro USB 케이블



식품의약품안전처

※ This certificate is issued on the Internet, you can check whether to forge or modify in homepage(emed.mfds.go.kr).
Furthermore, You can also check it by barcode exploiting document check program for scanner