

인정번호(No.) : KTC-BAAA-10100

의료기기 제조 및 품질관리 기준 적합인정서 (Certificate of GMP)

■ 업소명/허가번호 (Company name of Applicant / License No.)

자이글(주)
ZAIGLE Co.,Ltd.



■ 업소 소재지 (Company address of Applicant)

서울특별시 강서구 허준로 217, 1114호(가양동, 가양테크노타운 11층)
Rm1114, Gayang TechnoTown, 217, Heojun-ro, Gangseo-gu, Seoul, KOREA

■ 제조소명 (Name of Manufacturer)

제 조 자 : HUIZHOU GISUN ELECTRONICS CO.,LTD.

■ 제조소 소재지 (Address of Manufacturer)

제 조 자 : Xinjiao Gisun Industrial Park, Dong' ao Village, Shatian Town, Huiyang Disrtict,
Huizhou City, China

■ 품목군 (Category)

붙임참조 (See attached list)

의료기기 제조 및 품질관리기준에 적합함을 인정합니다.

(We hereby certify that the above manufacturer complies with Korea
Good Manufacturing Practices of Medical Devices for the product group listed above)

발행일자(Date of Issue) : 2020. 12. 31

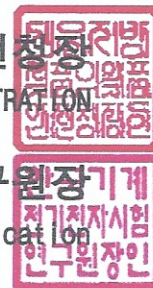
유효기간(Date of Expiration) : 2023. 12. 30



서울지방식품의약품안전청장
SEOUL REGIONAL FOOD AND DRUG ADMINISTRATION



한국기계전기전자시험연구원장
Korea Testing Certification



변경 및 처분 사항 등(Changes and Administrative measures)

년 월 일(Date)	내 용(Description)
2020-12-31	최초심사

인정번호(No.) : KTC-BAAA-10100

[붙임1]

순번(No.)	품목군(Name of Category)	비 고(Remarks)
1	생명유지 장치 Life Support System	
2	의료용 자극발생 기계기구 Machine or Instrument for Generating Electric Stimulation, Medical Use	

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인정번호(No.) : KTC-BAAA-10100

[붙임2]

시설물 상세정보

제조사

작업소 : Xinjiao Gisun Industrial Park, Dong' ao Village, Shatian Town, Huiyang Disrtict, Huizhou City, China

보관소 : Xinjiao Gisun Industrial Park, Dong' ao Village, Shatian Town, Huiyang Disrtict, Huizhou City, China

시험실 : Xinjiao Gisun Industrial Park, Dong' ao Village, Shatian Town, Huiyang Disrtict, Huizhou City, China

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