NO. 6210

License for Medical Device Manufacture Business

1. Company Name: AN Medical Co., Ltd.

2. Address: #103, 27 Dongmun-ro, Jeju-si, Jeju-do (Ildoil-dong, Dongmun Green Villa)

3. Representative (DOB): LEE, JEONGHYEON (December 18, 1956)

4. Quality Control Manager (DOB): LEE, JEONGHYEON (December 18, 1956)

5. Condition of License:

License is hereby given in accordance with Articles 6 and 15 of the 「Medical Device Act」 and Articles 3 and 29 of the Enforcement Decree of the same Act.

September 06, 2018

Re-issued

Gwangju Regional Office of Food and Drug Safety

Official Seal of the Office Head

※ This license was issued via internet and can be verified through the document verification number.
It can also be verified through the barcode in the lower part of the document (with a verification program for scanners)

Standard Number	Standard Name
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
ISO 14971:2019	Medical devices - Application of risk management to medical devices
IEC 60601-1:2005+A1:2012	Medical electric equipment – General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment), Medical electrical equipment - Part 1-2: General requirements for basic
IEC 60601-1-6:2010+A1:2013 for use in conjunction with IEC 62366:2007+A1:2014	Medical electrical equipment – Part 1-6 : General requirements for basic safety and essential performance – Collateral standard : Usability
IEC 62304:2006	Medical device software – Software life cycle processes
IEC 62133-2:2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications-part 2: Lithium systems
UN/DOT 38.3	Lithium metal and lithium ion batteries
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1 : General requirements
MFDS medical device regulations	Medical device regulations of ‘Ministry of Food & Drug Safety(MFDS)’ in Republic Of Korea