

Kalitest

CERTIFICATE OF REGISTRATION

This certificate has been awarded to the company

SAEHANUL BIOTECH CO., LTD.

**Room No.301, Sinwon Visiontower 88,Jeonpa-ro, Dongan-gu,
Anyang-si, Gyeonggi-do Korea**

To certify that the implemented medical devices quality management
system complies with

EN ISO 13485:2012

For the activities described below

**Design & Development, Production & Service of
Medical Light, Lamps, Otoscope and Throatscope**

Kalitest Certification and Training Services Ltd. Şti. :



Signed

Please verify the validity of this certificate with the serial number of 2106519 from the web site
of www.kalitest.com.tr or with TURKAK BDS NO from the web site of tbds.turkak.org.tr
KALITEST BELGELENDİRME VE EĞİTİM HİZMETLERİ LİMİTED ŞİRKETİ
Yazgülü Sokak, Aydın Sitesi 1.Kısım, C-4 1/D Blok, D:33, Levazım-Beşiktaş/İSTANBUL
www.kalitest.com.tr info@kalitest.com.tr

| | |
|------------------------|----------------------|
| Certificate No | K-MD-2036 |
| Date of Registration | 06.02.2020 |
| Period of Registration | 3 yıl / years |
| Certificate Date | 06.02.2020 |
| Expiry Date | 11.10.2021 |

The validity of this certificate depends
on the company's conformity with
KALITEST Certificate Regulations and
the result of the surveillance audits
which will be carried out
at least once in a year.

Certificate of conformity:

TÜV NORD

Registrier-Nr./Registered No.:

K1180/H05

| | | | | | |
|------------------------|---------------------|----------------|-----------------|---------------|-----------|
| Reference of applicant | Date of application | File reference | Test report No. | Date of issue | Revision: |
| - | 18.07.2005 | 82-05-P-168 | K2163/H05 | 25.08.2005 | 0 |

This is to certify that the technical documentation (doc. no: TCF-SO-01, rev. 0) for the following product(s) has been assessed and found in compliance with the essential requirements and relevant provisions of the Medical Device Directive (MDD) of the European Community of 14 June 1993 (93/42/EEC):

Certificateholder : SAEHANUL BIOTECH CORP.
#203 Youngpoong-Sangga, 130-1 Pyungchon-Dong,
Dong An-Gu, Anyang-Si, Kyungki-Do, Korea

Manufacturer : Same as above

Product : Otoscope

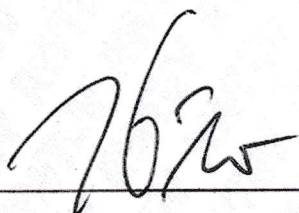
Classification : Class I Medical Device (Rule 12 acc. to Annex IX, MDD)

Type designation(s): SO-05R(Otoscope)
KLC-04 (Battery charger)

Standard(s) : EN 60601-1:1990+A1+A2
EN 60601-1-2:2001

This Certificate of Conformity is based on the evaluation of samples of the product. It does not imply an assessment of the production, and it does not permit the use of a mark of conformity or of a safety mark of TÜV NORD.

The holder of this certificate may use this Certificate together with his EC-Declaration of Conformity.



Signature of responsible
TÜV NORD product testing supervisor



TÜV NORD Korea Ltd.
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Fax : +82-2-6000-4223
E-mail: info@tuvnord.or.kr

Certificate of conformity

Registered No.:
K1170/H08

| Reference of applicant | Date of application | File reference | Test report No. | Date of issue | Expiry date |
|------------------------|---------------------|----------------|------------------------|---------------|-------------|
| | 03.03.2008 | KP-08-081 | K2155/H08 K2156/H08 | 23.05.2008 | - |

This is to certify that the following products have been assessed according to the standards as below and found in compliance with the essential requirements and relevant provisions of the Medical Device Directive (MDD) of the European Community of 14 June 1993 (93/42/EEC).

Product Operating LED Light

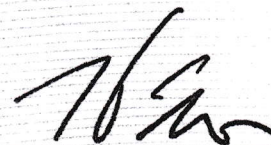
Classification: Class I Medical Device (Rule 12 acc. To Annex IX, MDD)

Type designation: SOL

Applicant: Saehanul Biotech Corp.
Room No. 301, Sinwon Visiontower, 898 Hogue-dong, Dongan-gu, Anyang-si, Kyungki-do 431-080, Korea

Standard(s): MDD Annex I Essential requirements
EN 60601-1:1990 + A1 + A2:1995
EN 60601-1-2:2001

This Certificate of conformity is based on the evaluation of samples of the product. It does not imply an assessment of the production and it does not permit the use of a mark of conformity or of a safety mark of the TÜV NORD CERT.



Certification Body for Product Safety

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