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. :

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.

TÜRKAK

TÜRKAK BDS NO
YS-6BE1-1A7E

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 TÜRKAK 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
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 superviser

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

TÜV NORD

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 Hogye-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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