



Declaration of Conformity

Issue date : December 11, 2013

Manufacturer's Name: SAEHANUL BIOTECH Co.,Ltd
Address: Room No.301, Sinwon Visiontower, 88
Jeonpa-Ro, Dongan-Gu, Gyeonggi-Do,
REPUBLIC OF KOREA
Tel.: +82-31-478-8766 Fax: +82-31-478-8768

EC-Representative: OPTOMIC ESPANA S.A.
C/Madrone 4F-Pol.Ind.La Mina 28770
Colmenar
Viejo-Madrid Spain
Tel.: +34 902 22 11 77 Fax: +34 902 22 11 78

Declares that the product:

P r o d u c t : Head lamp (Model Name : KS-02, KS-03,
KS-05)

Classification: According to CE LVD 2006/95/EC

We herewith declare that the above mentioned products meet the provisions of the Council Directive 2006/95/EC for low voltage device. All supporting documentation is retained under the premises of the manufacturer.

Standards applied: IEC 60335-1:2012

TESTING FACILITY: KESCO Safety Test Center
338-1, Yeonghwa-Dong, Jangan-Gu,
Suwon-City,
Gyeonggi-Do, 440-819, Korea

Place, Date of Issue : Gyeonggi-do, KOREA

Signature:

A handwritten signature in black ink, appearing to read 'Jung Taik Yong', written over a horizontal line.

Jung Taik Yong

President of SAEHANUL BIOTECH Co.,Ltd

Declaration Of Conformity

Manufacturer SAEHANUL BIOTECH CORP.
Address Room No.301, Sinwon Visiontower, 88, ,
Jeonpa-ro, Dongan-Gu, Anyang-Si, Gyeonggi-Do, Korea

Declares that the following product

Product Name : Rechargeable Head Lights with accessories (loupes, charger, cover assembly etc.)

Model Number SLL-01, SLL-02, SLL-03, SLL-05

Classification Class I Medical Device

Testing Facility TUV NORD Korea Ltd.

Testing report No. K2157/H08, K2158/H08 (Certificate No. K1171/H08)

Conforms to the technical regulations applicable to the product within the scope of
the Medical Device Directive 93/42/EEC

MDD EN60601-1:1990+A1+A2 : 1995
EN60601-1-2:2001

European Representative OPTOMIC ESPANA S.A.

Address C/Madrone 4F-Pol. Ind. La Mina 28770 Colmenar Viejo - Madrid, Spain
Tel : + 34 902 22 11 77 / Fax : + 34 902 22 11 78
info@optomic.com / www.optomic.com

This declaration is issued under the sole responsibility of the manufacture and,
If applicable, his authorized representative.

Point of Contact Taik-Yong, Jung, TEL:+82-31-478-8766, FAX:+82-31-478-8768

South Korea, Jan. 13, 2014



Taik-Yong, Jung/President



Declaration of Conformity

Issue date : June, 28, 2017

Manufacturer's Name: SAEHANUL BIOTECH Co.,Ltd

Address: Room No.301, Sinwon Visiontower, 88
Jeonpa-Ro, Dongan-Gu, Gyeonggi-Do,
REPUBLIC OF KOREA
Tel.: +82-31-478-8766 Fax: +82-31-478-8768

EC-Representative: OPTOMIC ESPANA S.A.

C/Madrono 4F-Pol.Ind.La Mina 28770
Colmenar
Viejo-Madrid Spain
Tel.: +34 902 22 11 77 Fax: +34 902 22 11 78

Declares that the product:

**Product : Head lamp (Model Name : KS-02, KS-03, KS-05)
with accessories** (Loupes, charging adapters KH-09, KH-10 and
holders KH-08, integrated batteries KH-01, belt clip battery packs with
cable KH-02)

Classification: Class I Medical Device

We herewith declare that the above mentioned products meet the provisions of
the Medical Device Directive (MDD) 93/42/EEC. All supporting documentation
is retained under the premises of the manufacturer.

Standards applied: EN 60601-1 : 2006, EN 60601-1-2 : 2007

TESTING FACILITY: KESCO Safety Test Center
338-1, Yeonghwa-Dong, Jangan-Gu,
Suwon-City,
Gyeonggi-Do, 440-819, Korea

Place, Date of Issue : Gyeonggi-do, KOREA

Signature:

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Jung Taik Yong

President of SAEHANUL BIOTECH Co.,Ltd.