



**Shantou Easywell Technologies Co.,Ltd**

Add: 6th Floor H5 Building, No.16 Lianjiang Road, Shantou, China Tel:0086-754-88784616

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## **EC Declaration of Conformity**

**Manufacturer:** Shantou Easywell Technologies Co.,Ltd

**Address:** 6th Floor H5 Building, No.16 Lianjiang Road, Shantou, China

**European Representative:** CELAB

**Address:** Via Maira snc 04100 Latina, Italy

**Product Name:** LED examination lamp, LED headlight

**Model:** KS-Q3, KS-Q5-5D, KS-Q7, KS-Q7E, KS-H1N, KS-W03

**Classification (MDD, Annex IX):** Class I

We herewith declare that the above mentioned products meet the transposition into national law, have been reviewed against the self-declaration requirements of conformity for CE marking

### **DIRECTIVES**

**General applicable directives:**

**Medical Device Directive:** COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC)

**Standard applied:**

EN ISO14971:2012 , EN ISO15223-1:2016 , EN1041:2008+A1:2013, EN60601-1:2006+A1:2013,  
EN60601-1-2:2015, EN60601-2-41:2009

**Shantou Easywell Technologies Co., Ltd.**

**General Manager: Justin**



Date: Nov.1st.2017