喬陽醫學科技
BIOCARE ASIA CO., LTD.

EU Declaration of Conformity

We, BIOCARE ASIA CO., LTD.
No.260,Mayun Road, New District, Suzhou, Jiangsu Province, PRC;
SRN: CN-MF-000016484, **as the manufacturer declare under our sole responsibility that the product:**

Product Name	:	Electric Lice Comb
Product Model	:	EL-1003
Classification	:	(EU)2017/745(MDR), Annex VIII, rule 13, Class I
Conformity Assessment Route	:	(EU)2017/745(MDR), Annex XI, Production Quality Assurance Medical Devices
European Representative	:	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80,20537 Hamburg,Germany
SRN of EU Rep.:		DE-AR-000000001
Application Date	:	Nov. 23,2021
GMDN code:		17552
Basic UDI – DI (EL-1003)		6922166460037

We, Biocare Asia CO, LTD declares that the above-mentioned product meets the provision of the Medical Devices Regulation (EU) 2017/745.

Biocare Asia Co., Ltd. 蘇州喬陽醫學科技有限公司

Nov. 23，2021
Date of Issue
Place of Issue: Jiangsu, P.R. China

Gino Chen
Quality Management Representative

喬陽醫學科技
BIOCARE ASIA CO., LTD.

This declaration also relates in conformity with the following standard(s) or other normative document(s):

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN 60601-1:2006/A1:2013 IEC 60601-1:2005/A1:2012	Medical electrical equipment-Part 1:General requirements for safety
EN 60601-1-2:2015 IEC 60601-1-2:2014 ANSI/AAMI 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-11: 2010	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 62366:2008	Medical devices - Application of usability engineering to medical devices.
EN60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 60601-1-6:2010
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected

	version 2017-03)
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
RoHS (2011/65/EU) RoHS (2011/65/EU) and its amendment directive (EU) 2015/863	Directive on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment
EMC (2014/30/EU)	electromagnetic compatibility
LVD (2014/35/EU)	electrical equipment designed for use within certain voltage limits

Intended purpose and classification justification:
The electronic lice comb is designed to remove lice and insect eggs from the head (scalp) hair. When comb the hair, it will produce a small charge that is not felt by humans, but it is fatal to lice. Once lice contact with comb teeth, they will die after electric shock!