CE Declaration of Conformity

Manufacturer:
Zhengzhou Huaer Electro-Optics Technology Co., LTD.
Floor 5, D of Building 18, The National University Science Park of Henan Province, China

European Authorized representative.
GloboDent Europe
c/Sant Elias, 40 Bajos.
08006-Barcelona, Spain

We, the manufacturer, herewith declare that the products

Model Number:
GB-PRO101 BlanQuest Pro Professional Treatment Kit UDI # 697404128PRO101JU
GB-HOM101 BlanQuest Home Kit UDI # 697404128HOM101E5
GB-LB101 LuxBrite Personal Teeth System UDI # 697404128ZLBS7
GB-LX105 LuxBrite Refill Kit UDI # 697404128BLBNF

Meet the provisions of the Council Directive MDR 2017/745 which apply to them

The Medical Devices has been assigned to class I according to Annex IV of the Directive MDR 2017/745. It bears the mark

CE

Conformity assessment procedure: Annex IV of Directive MDR 2017/745

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above-mentioned declaration of conformity is exclusively under the responsibility of

2022/06/16
Place, date
CE Declaration of Conformity

ZHENGZHOU HUAER ELECTRO-OPTICS TECHNOLOGY CO.,LTD 郑州华尔光电科技发展有限公司

David
Legally Binding signature, Function