

Declaration of Conformity

Product: ProPulse Electronic Ear Irrigator including associated Jet Tip

Name and address of the manufacturer:

Mirage Health Group Ltd.
11 Tewin Court, Welwyn Garden City, Hertfordshire, AL7 1AU, UK

This declaration of conformity relating to the above stated product is issued under the sole responsibility of the manufacturer.

It has been demonstrated that the requirements specified in Article 4 of 2011/65/ as amended 2015/863 have been met.

The object of this declaration described above is in conformity with the relevant Union harmonisation legislation provided that the equipment is, installed and used according to given instructions:

For European Union and Northern Ireland

Low Voltage Directive 2014/35/EU
EMC Directive 2014/30/EU
RoHS Directive 2011/65/ as amended 2015/863

for the United Kingdom

Electrical Equipment (Safety) Regulations 2016 for the United Kingdom
The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012

The following standards have been applied:

BS EN IEC 60601-1 with respect to safety
BS EN IEC 61000-3-2 Electromagnetic compatibility

Signed for and on behalf of:

Mirage Health Group Ltd.
11 Tewin Court, Welwyn Garden City, Hertfordshire, AL7 1AU, UK

Signature:

Date:

Name: Matt Blanchard

Function: Operations Manager