Declaration of Conformity to the

Medical Device Directive 93/42 EEC as amended 2007/47/EC

Class IIa
Product ProPulse Electronic Ear Irrigator including associated Jet Tip

This is to certify that the class IIa equipment specified above conforms to the above Directives as transposed in to national regulations and statutes of the United Kingdom, such compliance having been demonstrated via:

- A Technical File compliant to Annex VII
- Compliance to Annex II Full Quality Assurance
- Compliance to the Essential Requirements as per Annex I
- Machinery directive 2006/42/EC
- Quality Assurance procedures in accordance with BS EN ISO 13485:2016
- Safety in accordance with EN 60601-1
- Electromagnetic Compatibility in accordance with EN 60601-1-2

The CE marking of product being subject to the achievement and maintenance of an Annex II certification by BSI Notified Body 2797 located at Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands

The devices do not include animal or human tissue, derivatives thereof, blood products, products that would be considered to be medicinal products or phthalates as defined in annex I clause 7.5 nor are such materials used during their manufacture. This device is not considered Personal Protection Equipment.

This is to certify that the above statement is true and relates to product manufactured from this date.

Signed 

Name M Blanchard

Position Operations Manager

Date 04-02-2021

For and on behalf of Mirage Health Group Ltd. being a duly authorised officer of the manufacturer:

Company Name and Address:
Mirage Health Group Ltd
11 Tewin Court
Welwyn Garden City
Hertfordshire
AL7 1AU
United Kingdom

Medical Device Management Ltd EC REP
Block B, The Crescent Building,
Northwood, Santry, Dublin 9, D09 C6X8, Ireland