Declaration of Conformity to the:

- **European Medical Device Regulation 2017/745**

For the following Class I non-sterile, non-measuring devices:

- **ProPulse ProScoop**

Basic-UDI-DI for the above family: 506012449INS0040Z9

As the Manufacturer, Mirage Ltd hereby declares that the class I device (Annex VIII Rule 5) specified above is in conformity with the regulations stated, such compliance having been demonstrated via:

- Compliance to the General Safety and Performance Requirements as per 2017/745 Annex I
- A Technical documentation compliant to 2017/745 Annex II, III
- Declaration as per Article 19 and Annex IV
- Application of EN ISO 14971:2019 for the management of risks

The CE marking of product being subject to the appointment of a European Authorised Representative and registration with a European Competent Authority, which has been undertaken with the Irish Competent Authority, The Health Products Regulatory Authority, of Ireland.

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is to certify that the above statement is true and relates to product manufactured from the date specified and until superseded.

Signed Matt Blanchard

Digitally signed by Matt Blanchard
Date: 2023.07.12 12:22:57 +01'00'

Name

Position Operations Manager

Place at Welwyn Garden City

Signed for and on behalf of Mirage Ltd being a duly authorised signatory for the legal manufacturer and is issued under the sole responsibility of the manufacturer.

Manufacturer:	**Authorised Representative:**
Mirage Health Group 11 Tewin Court Welwyn Garden City AL7 1AU United Kingdom SRN GB-MF-000007803	Medical Device Management Ltd Block B, The Crescent Building, Northwood Santry Dublin 9 D09 C6X8 Ireland SRN IE-AR-000002496