

# **EUROPEAN UNION**

## **DECLARATION OF CONFORMITY**

**Manufacturer:** ReIngenuity, Inc.  
60 Baiting Place Road,  
Farmingdale,  
NY 11735  
USA

**SRN:** US-MF-000017554

**EU Authorised Representative:** Eurolink Europe Compliance  
Limited 25 Herbert Place  
Dublin  
D02 AY86  
Republic of Ireland

**SRN:** IE-AR-000002852

We the undersigned certify and declare under our sole responsibility that the following apparatus

**Conforming Apparatus:** Intraocular Pressure Reducer  
**GMDN:** 15048  
**Basic UDI-DI:** 0851607007HonanCH  
**Device Name and UDI-DI Numbers:** See Page 2 below  
**Risk Class:** Class I - MDR Annex VIII Rule 1  
**Technical Document Reference No:** TF-0001  
**Common Specifications** EN ISO 14971:2019 Medical Devices –  
Application of Risk Management to Medical  
Devices  
Medical Devices Regulations – Annex I, General  
Requirements

conforms to the requirements of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT  
AND OF THE COUNCIL of 5 April 2017 on medical devices

**Signed:**   
R. Reardon, President ReIngenuity, Inc.

**Date:** 11<sup>th</sup> July 2025

**Issued:** New York, USA

| <b>Device Name</b>  | <b>Device Model</b> | <b>Device UDI-DI</b> |
|---|---------------------|----------------------|
| GAUGE, CASE, TUBING, WITH REUSABLE BELLOWS & HEADBAND   | 2050                | 00851607007004       |
| GAUGE, CASE, TUBING, WITH REUSABLE BELLOWS & HEADBAND + RELIEF VALVE                                    | 2055                | 00851607007011       |
| GAUGE (LATEX FREE), CASE, SILICONE TUBING WITH 1 BOX (12) DISPOSABLE BELLOWS & HEADBANDS                | 3000                | 00851607007226       |
| GAUGE (LATEX FREE), CASE, SILICONE TUBING + RELIEF VALVE WITH 1 BOX (12) DISPOSABLE BELLOWS & HEADBANDS | 3005                | 00851607007233       |
| 1 BOX (12) SINGLE USE DISPOSABLE BELLOWS & HEADBANDS  | 701                 | 00851607007219       |
| 3 BOXES (36) SINGLE USE DISPOSABLE BELLOWS & HEADBANDS  | 703                 | 00851607007216       |
| BELLOWS (REUSABLE)  | 150                 | 00851607007028       |
| DIVIDED HEADBAND  | 210                 | 00851607007042       |
| TUBING  | 300                 | 00851607007059       |
| SILICONE TUBING   | 325                 | 00851607007240       |
| RELIEF VALVE  | 400                 | 00851607007066       |
| PRESSURE GAUGE & BLACK BULB AIR PUMP (LATEX)  | 500                 | 00851607007073       |
| PRESSURE GAUGE & BLUE BULB AIR PUMP (LATEX FREE)  | 505                 | 00851607007080       |
| KNURLED KNOB  | 510                 | 00851607007097       |
| CRYSTAL (PLASTIC GAUGE COVER)   | 515                 | 00851607007103       |
| FERRULE & LUER CONNECTOR  | 520                 | 00851607007110       |
| FERRULE   | 525                 | 00851607007127       |
| CHECK VALVE (NEW STYLE)   | 530                 | 00851607007134       |
| CHECK VALVE FILTER (OLD STYLE)  | 535                 | 00851607007141       |
| CHECK VALVE (ONE PIECE DESIGN)  | 541                 | 00851607007158       |
| SCREWS FOR PALM REST (EACH)   | 543                 | 00851607007165       |
| BLACK BULB - AIR PUMP(LATEX)  | 550                 | 00851607007172       |
| BLACK BULB W/ FILTER & RING (NEW STYLE)   | 560                 | 00851607007202       |
| CASE, BLACK W/ ZIPPER   | 600                 | 00851607007257       |