

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, Director
ReIngenuity, Inc.


[Robert Reardon \(Jun 5, 2024 11:39 GMT+1\)](#)

Date: 4 June 2024

Issued: Dublin, Ireland

Device Name	Device Model	Device UDI-DI
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

EMC DIRECTIVE Declaration of Conformity:

Final Audit Report

2024-06-05

Created:	2024-06-05
By:	Sharon Head (sharon@eurolink-europe.co.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAfVEp6TJmdnk3SchfvOLgtec-T_AcOm-b

"EMC DIRECTIVE Declaration of Conformity:" History

-  Document created by Sharon Head (sharon@eurolink-europe.co.uk)
2024-06-05 - 9:15:00 AM GMT
-  Document emailed to Robert Reardon (rjr@reingenuity.com) for signature
2024-06-05 - 9:15:04 AM GMT
-  Email viewed by Robert Reardon (rjr@reingenuity.com)
2024-06-05 - 10:38:57 AM GMT
-  Document e-signed by Robert Reardon (rjr@reingenuity.com)
Signature Date: 2024-06-05 - 10:39:22 AM GMT - Time Source: server
-  Agreement completed.
2024-06-05 - 10:39:22 AM GMT