

# Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the manufacturer.

|  |   |
|--|---|
| CERTIFICATE HOLDER / MANUFACTURER:                               | Southland Sensing Ltd.  |
| CERTIFICATE HOLDER / MANUFACTURER ADDRESS & CONTACT INFORMATION: | 4045 E. Guasti Rd. Suite 203<br>Ontario, CA 91761<br>U.S.A.<br><br>TEL: 1-949-398-2879<br>E-MAIL: office@sso2.com |
| DIRECTIVES / STANDARDS TO WHICH CONFORMITY IS DECLARED:          | ISO 13485:2016<br>ISO 9001:2015<br>ISO 80601-2-55   |
| EXPIRATION DATE:   | 2028_April_18 (ISO 13485:2016)<br>2027_March_15 (ISO 9001:2015)   |
| TYPE OF PRODUCTS:  | MED-19 Oxygen Analyzer<br>Medical Oxygen Sensors - See Appendix A<br>Disposable Tee Adapter                       |
| CLASSIFICATION:  | Device(s) are IIb Classified  |
| NOTIFYING BODY:  | Perry Johnson Registrars, Inc.<br>755 West Big Beaver Rd. Suite 1340<br>Troy, Michigan 48084                      |
| CERTIFICATE NUMBER(S):   | C2025-01578 (ISO 13485:2016)<br>C2024-01580 (ISO 9001:2015)   |

I, the undersigned, hereby declare and assume the responsibility that the products are traceable by date code & serial number and are in compliance with the above referenced directive(s) / standard(s).

Signature:



Full Name:

Benjamin Barker

Position:

President

Date:

January 1, 2023

Place:

Ontario, California, U.S.A.

# APPENDIX A

## LIST OF OXYGEN SENSOR(S) / ANALYZER (S).

| Model Name: | Product Description   | Classification: | UMDNS nO | UDI / GTIN No. |
|-------------|-----------------------|-----------------|----------|----------------|
| MED19       | Oxygen Monitor        | IIb             | 12858    | 00850058371252 |
| TA-01       | Disposable Tee Adater | IIb             | 12958    | M996BE1251TD0  |
| OKS-1       | Oxygen Sensor         | IIb             | 113538   | 00850058371009 |
| OKS-2       | Oxygen Sensor         | IIb             | 113538   | 00852258371016 |
| OKS-3       | Oxygen Sensor         | IIb             | 113538   | 00850058371023 |
| OKS-4       | Oxygen Sensor         | IIb             | 113538   | 0085005837103  |
| OKS-5       | Oxygen Sensor         | IIb             | 113538   | 00852258371047 |
| OKS-6       | Oxygen Sensor         | IIb             | 113538   | 00850058371054 |
| OKS-11      | Oxygen Sensor         | IIb             | 113538   | 00850058371085 |
| OKS-12      | Oxygen Sensor         | IIb             | 113538   | 00850058371092 |
| OKS-13      | Oxygen Sensor         | IIb             | 113538   | 00850058371108 |
| OKS-14      | Oxygen Sensor         | IIb             | 113538   | 00850058371115 |
| OKS-15      | Oxygen Sensor         | IIb             | 113538   | 00850058371122 |
| OKS-19      | Oxygen Sensor         | IIb             | 113538   | 00850058371269 |
| OKS-21      | Oxygen Sensor         | IIb             | 113538   | 00850058371139 |
| OKS-23      | Oxygen Sensor         | IIb             | 113538   | 00850058371276 |
| OKS-39      | Oxygen Sensor         | IIb             | 113538   | 00850058371238 |
| OKS-250     | Oxygen Sensor         | IIb             | 113538   | 00850058371160 |
| OKS-250B    | Oxygen Sensor         | IIb             | 113538   | 00850058371177 |
| OKS-250D    | Oxygen Sensor         | IIb             | 113538   | 00850058371184 |
| OKS-250E    | Oxygen Sensor         | IIb             | 113538   | 00850058371191 |
| OKS-250F    | Oxygen Sensor         | IIb             | 113538   | 00850058371207 |
| OKS-250G    | Oxygen Sensor         | IIb             | 113538   | 00850058371214 |
| OKS-250K    | Oxygen Sensor         | IIb             | 113538   | 00850058371221 |
| OKS-915     | Oxygen Sensor         | IIb             | 113538   | 00850058371146 |
| OKS-915C    | Oxygen Sensor         | IIb             | 113538   | 00850058371153 |
| OKS-915G    | Oxygen Sensor         | IIb             | 113538   | 00850058371245 |

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