

## Product Specifications Sheet

|                        |                                      |            |     |                                                                                     |
|------------------------|--------------------------------------|------------|-----|-------------------------------------------------------------------------------------|
| Specification Sheet No | SSN-JFRU06-010                       |            |     |  |
| Product Name           | Suction                              |            |     |                                                                                     |
| Product Description    | Universal Oxygen Bubble Tube         |            |     |                                                                                     |
| Range                  | Universal                            |            |     |                                                                                     |
| Manufacturer           | Romsons International                |            |     |                                                                                     |
| Material               | Polyvinyl Chloride and Polypropylene |            |     |                                                                                     |
| Sterilisation          | Non-sterile                          |            |     |                                                                                     |
| Issue Date             | 21st May 2024                        | Version No | R02 |                                                                                     |

|              |                                                                                                                                                                                 |
|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Intended use | Oxygen bubble Tube is intended for oxygen delivery, applications. The tube length can be modified by cutting at the bubble for connection adaption purposes, single use device. |
|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| Packaging    |        |                  |                             |                |                      |
|--------------|--------|------------------|-----------------------------|----------------|----------------------|
| Product Code | Colour | Length (Approx.) | Internal Diameter (Approx.) | Items Per Pack | Qty – Shipper Carton |
| UN880        | Green  | 30 m             | 3 mm                        | 1              | 30                   |
| UN881        |        | 100 m            | 3 mm                        | 1              | 100                  |

|                                                                                                                   |                                                                                                                                                                                                                                                     |      |   |
|-------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|---|
| Quality Certification                                                                                             | ISO 13485:2016                                                                                                                                                                                                                                      |      |   |
| Device Classification                                                                                             | Class I                                                                                                                                                                                                                                             | Rule | 2 |
| Conformity Route                                                                                                  | Medical Devices Directive (93/42/EEC)                                                                                                                                                                                                               |      |   |
| Storage conditions                                                                                                | Store in a cool dry place away from heat and direct sunlight                                                                                                                                                                                        |      |   |
| Shelf life                                                                                                        | 5 Years from manufacturing date if stored as recommended                                                                                                                                                                                            |      |   |
| Contraindications/Warnings                                                                                        | To be administered by an expert qualified medical professional.<br>Discard after Single Use.<br>For Single Use Only                                                                                                                                 |      |   |
| Markings                                                                                                          | Universal Logo, Ref, Product name, Lot, Barcodes, Manufacture date, Expiry date, CE Mark, Latex free, Non-sterile, DEHP free, Medical device, keep dry, keep away from sunlight, Handle with Care, Manufacturer Name & Address, Distributor contact |      |   |
| Additional information                                                                                            | Product is Latex-free                                                                                                                                                                                                                               |      |   |
| Medical Device and Reporting System: Incidents caused by this device must be reported immediately to our offices. |                                                                                                                                                                                                                                                     |      |   |

The information provided within this Specification Sheet is correct as of last revision but it is subject to change without notice.

|                                                            |                                  |
|------------------------------------------------------------|----------------------------------|
| 365 Healthcare                                             | Mediq House                      |
| T: +44 (0) 1332 413 700                                    | Arundel Avenue, Castle Donington |
| W: <a href="https://mediq.co.uk/">https://mediq.co.uk/</a> | Derby, DE74 2HJ                  |

365 Healthcare is a trading division of Mediq Healthcare UK Ltd  
Registered in England No. 62537

| Document Reference | Document Name               | Reviewed By   | Approved By  | Revision Number | Issue Date                 |
|--------------------|-----------------------------|---------------|--------------|-----------------|----------------------------|
| DMS 04-004         | Product Specification Sheet | Ashley Miller | Racheal Begg | R01             | 12 <sup>th</sup> June 2023 |

## Amendment Record

This procedure is reviewed to ensure its continuing relevance to the system and process that it describes. A record of contextual additions or omissions is given below. This revision history lists all changes to this document, the date of each revision, and the reason for each revision.

| Revision Number | Revision Date | Reason for Revision                        | Updated by           |
|-----------------|---------------|--------------------------------------------|----------------------|
| R01             | 21/05/2024    | New SSN Mediq Healthcare UK brand Template | Elizabeth Ogunkolade |
| R02             | 21/05/2024    | Update Mediq Healthcare UK address         | Jack Wong            |
|                 |               |                                            |                      |

This document is uncontrolled when printed. The master document is controlled electronically, and document users are responsible for ensuring printed copies are valid prior to use to ensure it represents current practice within Mediq Healthcare UK Ltd.