

## Instructions for Use: Self-Looping labels IFU

| Brand Name of Product                | Self-Looping Labels  |
|--------------------------------------|--|
| Generic Name of Product              | Tray labels  |
| Product Code Number(s)               | 403005, 403115, 403125, 403225, 403225-QTO, 404225-351-GI, 403225 LNR, 403225            |
|                                      | PK, 403225 RD, 403225 RD-BIO, 403225 SLOTTED, 403225 SLOTTED PINK, 403225                |
|                                      | YL, 403225 BL, 403225 GN, TAG-CONTAIN2   |
| Purpose of Product                   | These labels facilitate specific markings and remarks for the sterile containment trays. |
|                                      | They are designed to minimize misunderstandings about the contents of an instrument tray |
|                                      | and to notify about the maintenance of an item.  |
| Range of Applications for Product    |  |
| <b>Key Specifications of Product</b> | Self-looping style for mounting on the handle of any closed container                    |
|                                      | Compatible with steam, EO and VHP sterilization  |
|                                      | Available in a variety of colors   |

| Shipping & Storage        |                      |  |
|---------------------------|----------------------|--|
| Shipping Conditions &     |                      |  |
| Requirements              |                      |  |
| <b>Storage Conditions</b> |                      |  |
| Packaging Contents        | Packaged 500 per box |  |
| Shelf Life                |                      |  |

| Instructions for Using Product           |  |  |
|--|--|--|
| Description of Use(s)                    | The PET- based label is suitable for sterilization and are resistant to washing and  |  |
|  | disinfection and thus can go through the reprocessing cycle.   |  |
| Preparation for Use                      |  |  |
| Diagrams (drawings, pictures)            |  |  |
| Steps for Use of Product                 | 1. Loop the tray label through the handle of the container or tray.  |  |
|  | 2. When using slotted tray label, push the count sheet through the tray label so it is   |  |
|  | hanging evenly. You can also affix an ID label to the front of the tag.  |  |
| Interpretation of Results                |  |  |
| <b>Contraindications of Test Results</b> |  |  |
| Documentation                            |  |  |
| Special Warnings and Cautions            | <ul> <li>Tray labels should not be in physical contact with surgical instruments during sterilization cycles.</li> <li>Tray labels should not be blocking any vent holes in trays as this may interfere</li> </ul> |  |
|  | with sterilization.  |  |
|  | Do not handle tray labels until they are allowed to cool down to room temperature after sterilization or thermal disinfection.   |  |
| Disposal                                 |  |  |

| Reprocessing Instructions            |   |
|--------------------------------------|---|
| Point of Use                         |   |
| Preparation for Decontamination      |   |
| Disassembly Instructions             |   |
| Cleaning – Manual                    |   |
| Cleaning – Automated                 |   |
| Disinfection                         |   |
| Drying                               |   |
| Maintenance, Inspection, and Testing |   |
| Reassembly Instructions              |   |
| Packaging                            |   |
| Sterilization                        | Compatible with steam, EO and VHP sterilization.  |
|                                      | <ul> <li>Recommended cycle time for steam sterilization is 270°F for 4 minutes / 275°F</li> </ul> |
|                                      | for 3 minutes.  |

| Storage                |  |
|------------------------|--|
| Additional Information | Make sure the label is hanging freely from the tray handle and not blocking holes in the |
|                        | tray.  |

| Related Healthmark Products     |                                     |
|---------------------------------|-------------------------------------|
| Other Product Support Documents | Labels Brochure, Labels Price List  |
| Reference Documents             |                                     |
| <b>Customer Service Contact</b> | Healthmark Industries Company, Inc. |
|                                 | 18600 Malyn Blvd.                   |
|                                 | Fraser, MI 48026                    |
|                                 | 1-586-774-7600                      |
|                                 | healthmark@hmark.com                |
|                                 | hmark.com                           |