Revision History for PRC097208

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| **SUMMARY OF CHANGES** | |
| Revision No. | Description of Change |
| A | Original document |

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| --- | --- |
| **INSTALLATION QUALIFICATION REPORT** | |
| **Document Title:** | Installation Qualification Report for Bulk Packaging Smart System, Bulk Packaging Weight Scale & Label Printer |
| **Document Number / Revision:** | PRC097208 Rev A |
| **Site / Location:** | Independencia: Ethicon Endo-Surgery, S.A. de C.V. Planta II, Calle Durango No. 2751, Colonia Lote Bravo, Ciudad Juárez, Chihuahua, 32575, México |
| **Project / Area:** | Megadyne Packaging Line 174 |
| **Equipment:** | Bulk Packaging Smart System, Bulk Packaging Weight Scale & Label Printer |
| **Equipment Supplier:** | Prod Design / Zebra Technologies |
| **Reference IQ Protocol:** | PRC097206 Rev A |
| N/A | |

# Document Approvals

Ethicon Endo Surgery

CP0160: Report – Installation Qualification

Governance: Lifecycle Engineering

| Function | Name | Signature | Date |
| --- | --- | --- | --- |
| **Originator** | Amada Cabildo Mena | eSig in EPIcenter System | Electronic Date in EPIcenter System |
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| Lifecycle Quality Engineer | Ihsan Samara | eSig in EPIcenter System | Electronic Date in EPIcenter System |

# Purpose

The purpose of this Installation Qualification Report is to document the objective evidence that equipment listed below for the Megadyne line 174 in Indenpendencia Plant:

* E20295 Bulk Packaging Smart System, Maximo ID ES4377
* E20296 Bulk Packaging Weight Scale, Maximo ID ES4378
* E20129 Printer A, Maximo IDs ES4373 & ES4374

Have been installed correctly, safely and met the Installation Requirements in accordance with the specifications applicable to the EES procedures.

# Scope & Background

The scope of this Installation Qualification is limited to E20129 Printer A MaxIDs ES4373 & ES4374, E20295 Bulk Packaging Smart System MaxID ES4377 and E20296 Bulk Packaging Weight Scale MaxID ES4378 installed in production Megadyne Packaging Line 174.

All activities of this report are limited to the product codes listed in Table 1.

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| --- | --- |
| Code | Description |
| 0012 | EZ Clean 2.5" Blade |
| 0012A | EZ Clean 2.75" Blade |
| 0012AM | EZ Clean 2.75" Modified Blade |
| 0014 | EZ Clean 6.5" Blade |
| 0014A | EZ Clean Blade, 4.0" |
| 0014AM | EZ Clean Modified Blade, 4.0" |
| 0014M | EZ Clean Modified Flat Blade, 6.5" |
| 0012M | EZ Clean 2.5" Modified Blade |
| 0013 | EZ Clean 2.75" Needle |
| 0013M | EZ Clean Modified Needle, 2.75" |
| 0118 | EZ Clean Sharp Needle, 2.0" |
| 0118A | EZ Clean Sharp Needle, 2.5" |
| 0012MBN | EZ Clean Modified Flat Blade, BNS, 2.5" |
| 0012BN5 | EZ Clean Flat Blade, BNS, 2.5" (Quantity 500) |
| 0012ABN | EZ Clean, Bulk NS, 2.75" (Quantity 100) |
| 0014BN | EZ Clean Blade, 6.0", BNS |
| 0012AMBN | EZ Clean, Modified Blade, Bulk NS, 2.75" |
| C012ABN | EZ Clean, 2.75", Custom Exposure, Bulk Non-Sterile (QTY 100) |

**Table 1: Product Codes for Packaging**

## Equipment information

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Equipment Name | Equipment Number | Maximo ID Number | Supplier | Serial Number |
| Bulk Packaging Smart System | E20295 | ES4377 | Prod Design | N/A |
| Bulk Packaging Weight Scale | E20296 | ES4378 | Prod Design | N/A |
| Printer A | E20129 | ES4373 | Zebra Technologies | 71J195100374 |
| ES4374 | 71J200200217 |

**Table 2: Equipment Information**

## Process information

Zebra printers E20129, are intended to perform the function of printing and dispensing labels for packaging product codes. Bulk Packaging Weight Scale E20296 and Bulk Packaging Smart System E20295 are intended to ensure that the product weight is in weight conformance according to the defined product code weight.

## Product information

Products applicable for this Installation Qualification Report are listed in Table 1.

## Out of Scope

All equipment and product not listed or mentioned in this installation qualification report.

# Executive Summary

Installation Qualification (IQ) has been completed for the equipment listed in Table 2, located in Independencia Plant, Ethicon Endo, following IQ Protocol PRC097206 Rev A. There were no deviations generated.

The IQ acceptance criteria defined in PRC097206 Rev A, were satisfactorily met, as summarized in Attachment 2. The testing conducted established that all key aspects of the equipment listed in Table 2 of this report are suitably considered, and the functional/operational capabilities have been verified.

# Deviations

No validation deviations were generated during the execution of the protocol. All tests met the requirements of the protocol.

# Conclusion

The Installation Qualification has established by objective evidence that all key aspects of the equipment listed in Table 2 of this Installation adhere to the EES approved specifications and that the recommendations of the supplier of the equipment have been suitably considered.

The Installation Qualification has met acceptance criteria in the protocol based on the requirements in PR-0000089 Franchise Procedure for Validation (Shared).

# AttachmentS

|  |  |
| --- | --- |
| Attachment No. | Title |
| Attachment 1 | New Equipment Sheet FMWE0366.3 |
| Attachment 2 | Executed Installation Qualification Protocol |
| Attachment 3 | Maximo Evidence |
| Attachment 4 | Training Record Form FM-0000809 |
| Attachment 5 | Calibration Records |
| Attachment 6 | Preventive Maintenance Records |
| Attachment 7 | EHS assessment |
| Attachment 8 | Equipment Drawing |
| Attachment 9 | Spare part List |