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M-b-378
Supplement 1

May 12, 2020

TO: Director, Office of State Cooperative Programs
Attn: Office of State Cooperative Programs, Division of Milk Safety
Management and Staff

FROM: Milk and Milk Products Branch (HFS-316)

SUBJECT: Agri-Service LLC Dairy Heritage Flow Diversion Control System Version 1.16 Model Number: 66-03400-000 name change to Conovale Controls Pressure Differential Control, Version 2.2, Model Number 66-03400-000.

In accordance with M-I-00-2, *Milk and Milk Product Equipment-A Guideline for Evaluating Construction*, FDA's Milk Specialists and CFSAN's Milk and Milk Products Branch have specifically evaluated the Agri-Service LLC Dairy Heritage Flow Diversion Control System Version 1.16 Model Number: 66-03400-000 and have validated and confirmed the technical information submitted by Agri-Service LLC and reviewed by the Atlantic Midwest Dairy Equipment Review Committee (AMDERC).

The Agri-Service LLC Dairy Heritage (Conovale Controls) Flow Diversion Control System is **composed of a pair of DEFINOX Model number DCX4 valves, as the flow diversion device (FDD)**, along with a control box, which has been designed to comply with Item 16p(B)-High- Temperature-Short-Time (HTST) Continuous-Flow Pasteurization of the *Grade "A" Pasteurized Milk Ordinance (PMO)*. The technical design and supporting documentation submitted to AMDERC and FDA for review were for the 1.5 - 4 inch DEFINOX valve which make up the FDDs.

When constructed, installed, operated and maintained as described in this memorandum, the Agri-Service LLC Dairy Heritage (Conovale Controls) Flow Diversion Control System Version 1.16 Model Number: 66-03400-000 has been found to comply with the applicable provisions of Item 16p(B) of the PMO. Compliance with the PMO is based upon construction, installation, operation and maintenance criteria as cited in Agri- Service LLC Dairy Heritage Flow Diversion Control System Version 1.16 Model Number: 66-03400-000 Operations and Maintenance Manual Publication Rev 1.1, dated 06/14/2016, and the following provisions:

1. The installation shall comply with all applicable Tests cited in Appendix I – Pasteurization Equipment Controls – Tests of the PMO.
2. Upon the proper installation and the determination of compliance through

appropriate required PMO testing, regulatory seals shall be applied.

The technical information addressing the Agri-Service LLC Dairy Heritage (Conovale Controls) Flow Diversion Control System Version 1.16 Model Number: 66-03400-000 constitutes AMDERC's Engineering Design and Technical Construction File (EDTCF). The material in the EDTCF is the property of the manufacturer and may be provided at their discretion. For additional information regarding this piece of equipment please contact:

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FDA's review and acceptance of the Agri-Service LLC Dairy Heritage (Conovale Controls) Flow Diversion Control System Version 1.16 Model Number: 66-03400-000 does not constitute FDA or Regulatory Agency endorsement or approval. Any representation on a label or in printed literature citing or indicating as "FDA Approval" would be considered as false and misleading.

With this Supplement, the company's name was changed from "Agri Service LLC" to "Conovale Controls", and the contact information was updated.

Please note that upon the issuance of this M-b-378 (Supplement 1), M-b-378, issued January 26, 2018, will be classified "**INACTIVE**".

An electronic version of this memorandum is available for distribution to FDA Milk Specialists, Milk Regulatory/Rating Agencies, and Milk Sanitation Rating Officers. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will also be available on the FDA Web site at <http://www.fda.gov> at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to monica.metz@fda.hhs.gov.



Monica Metz, Chief
Milk and Milk Products Branch

Attachments:
Dairy Heritage Flow Diversion Control System, Version 1.16, Rev 1.1, dated 06/14/2016



Flow Diversion Control System

Version 1.16



Rev.1.1 06/14/2016

Section 4 – Regulatory Seals

4.1 Enclosure Sealing

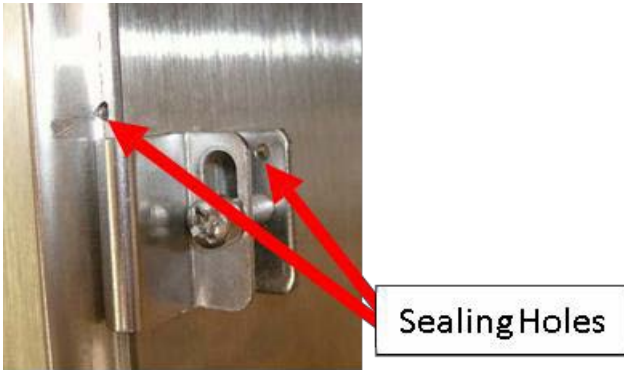


Figure 4.1a. Enclosure sealing

Section 5 – Testing

The Dairy Heritage Flow Diversion Device is to be tested in accordance with the procedures set forth in the current PMO, Appendix I.