

Product Change Notification

Product Change #: PCN313

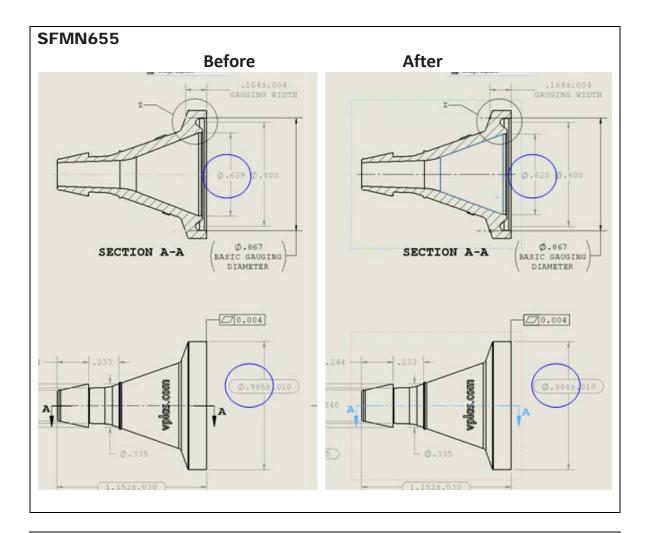
Posting Date: 02/08/2016

Description of Change:

Nordson Medical (Value Plastics) is changing their SFMN655-6005 and SFMN655-J1A Mini sanitary fittings to be compliant with the currently published ASME BPE 2014 standard with respect to Table DT-7-1 Hygienic Clamp Ferrule Standard Dimensions and Tolerances; DT-9.3-1 Hygienic Clamp Ferrule Design Criteria and PM-4.6.1.2 Performance Note.

It is important to note that the raw materials and finished good part numbers are not changing. Changes include documentation changes, adding a new measurement to the mini end cap print and minor changes to the nominal ID and OD dimensions of the sanitary fittings to bring them into full ASME BPE compliance. These changes are intended to be in alignment with the ASME BPE standard and should not impact the performance of the fittings. These changes will be made over the course of the next xx months. Please see the scheduled below for more details about the current expected implementation timeframes for each part.

Please see the attached table for the specifics of the change. The implementation of these changes will follow an internal schedule and compliant fittings will be launched as completed. The changed product will be distinguished by lot numbers.



Reason:

This ASME (American Society of Mechanical Engineers) standard incorporates the industry best practices and provides the requirements applicable to the design of equipment used in the Bioprocessing and pharmaceutical industries.

Nordson Medical is a firm supporter of the ASME BPE standard and the impact it has in bringing a better quality hygienic union to the market. The change applicable to all maxi and mini fittings offered is only to the nominal dimensions at this time; tolerances as present in the standard is only applicable to metal fittings and is not established for products made of polymeric materials.

Parts Affected: SFMN655-6005 SFMN655-J1A

Effective Date: 03/07/2016

Implementation Procedure:

The priority of implementation of these changes are as below

1. First and immediate are the SFMN655-6005, SFMN655-J1A, Since these changes will not impact these products interworking with other products such as bag ports, filter canisters, or pumps etc; these changes will be done on a rolling basis, existing inventory

will not be scrapped for the Maxi sizes but will be for the Mini version impacted by this change.

The changed product will be distinguished by the lot number. Dimensional verification is needed to support compliance as stated above.