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Product Change Notification

Product Change #: PCN311B

Posting Date: April 8, 2016

Description of Change:

These products will undergo a change with respect to the housings used in these assemblies. These housings will now be annealed to reduce the high molded-in stresses caused during the molding process. Root cause and problem solving analyses has proven that annealing the housings significantly reduce these molded-in stresses, preventing possible environmental related stress cracks from occurring.

It is important to note that the annealing of the housings will be implemented together with the changes as communicated previously through Product Change Notification PCN311 as applicable. This is done to our customers benefit so that they can perform their validations just once.

It is important to note that the product dimensions, raw materials, and finished good part numbers will not change with the addition of the annealing process.

Reason:

Molded in stresses generated during the molding process, when exposed to solvent during the bonding process, have the possibility of generating environmental stress cracks in the affected assemblies. Validation testing and accelerated stress tests have proven that the addition of an annealing process practically eliminates any chances for environmental stress crack formation as a result of the solvent bonding process.

Parts Affected:

FCA028-001, FCA040-001, FCA049-001, FCA047-001, CA260-001 and CA261-001

Effective Date:

Please see table as below for when validation samples are available. For the following SKUs, shipment of PCN311B product with annealed housings will start after current inventory depletion. FCA028-001, and FCA040-001



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Implementation Procedure:

An annealing process will be added to the manufacturing process to prevent environmental stress cracking of these housings. This will be completed together with the implementation of the PCN311 changes.

PCN311 and PCN311B products will have lot numbers starting with 161....

Nordson Medical P/N: FCA049-001

1. Roll in PCN311 with annealed housings.

Nordson Medical P/N: CA260-001

1. Roll in PCN311 with annealed housings.

Nordson Medical P/N CA261-001

1. Roll in PCN311 with annealed housings.

Nordson Medical P/N FCA028-001

1. Roll in PCN311 with annealed housings.

Nordson Medical P/N FCA040-001

1. Roll in PCN311 with annealed housings.

The table below provides the validation sample availability dates.

Assembly	Date Validation Samples are Available
FCA049-001	Available
CA260-001	Available
CA261-001	Available
FCA028-001	April 1
FCA040-001	April 1