

Change Notification Letter

Notification date: DD Month YYYY hh:mm:ss

Notification Number: CCNS-1234567 or NC-12345678 or CN-12345678

Change Control Number: e. g. 12345 or TW 123456

The purpose of this notification is to inform you of a change impacting product(s) for which a change commitment / agreement has been established.

If there is a subsequent Change Notification, the follow-up Notification Number receives the suffix-2 (or higher) (e. g. CCNS-1234567-2). On follow-up notifications the opening paragraph is replaced with the following paragraph:

This notification is a follow-up to a change notification previously sent on DD Month Year. If your company did not receive the previous notification(s), it is possible your company had not established a change commitment / agreement at the time of the previous notification(s).

Affected Product(s)

This section shows a list of all product numbers and product names which are affected by the change and for which our customers have opted in. This means that each customer receives a customized product list, reflecting the products under agreement. The number of the respective QAA or CNC is given in column Related Contracts.

This Change Notification is related to

As discussed in the Notifiable Events Matrix, we notify our customers of changes as defined by the quality attributes of the chosen products. This section states the change types which apply to this change: e. g. Change in Specification, Obsolescence, or Labelling. Multiple selections are possible.

Description of Change

This section defines the change. There may be a list of changing parameters facilitating pre- and post-change comparison.

Reason of Change

Transparency is a primary goal for notifying our customers regarding changes. Therefore, this section describes the circumstance which led to the implementation of the respective change(s), e. g. obsolescence of a product, changes in shelf life, raw material changes due to supplier issues, packaging optimizations etc.

Implementation Date/Batch Number

Depending on the type and nature of the change, the product's MQ Level, and the agreements in a CNC or QAA we use best efforts to send our Change Notifications with a reasonable lead time. On occasion, due to unforeseen circumstances, an immediate implementation may be required.

To allow our customers a better overview of their pre- and post-implementation materials, this section offers information regarding when the change is expected to be implemented and the affected batch number if it is available. It is of course in our interest to inform our customers as early as possible about upcoming changes. However, it can happen that at the time of notification the number of the last batch before change or a first batch after change is not yet known exactly when the notification letter is sent to our customers. The prospective implementation date is provided in such cases.

Additional Information

This section informs our customers about the availability of qualification samples, if applicable and the availability of Validation or Qualification Reports or a Customer Summary Report with extended background explanations and a results summary.

This section may also inform our customers of pre- and post- Change batches. If the Change is implemented while the Company holds in-stock pre-Change batches, customers may receive pre-Change batches after the Change implementation date, while newly produced batches comply with the post-Change conditions.

In this section, we may also inform our customers about what parameters will **not** be influenced by the change.

Attachments

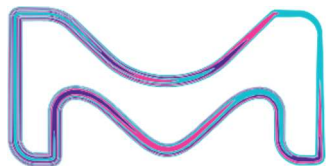
If attachments, like Customer Summary Reports or other documents, are sent out together with the Change Notification, they are indicated here.

Change Notifications are often sent out far ahead of a Quality documentation Change (e. g. CoA/CoQ/Label Change). Therefore, documents with post-Change alterations typically cannot be sent together with the letter for customer information. Due to Quality Management reasons, we must not create post-change documents before the change is implemented. In such cases, the post-Change document samples can be obtained upon request after the change implementation date. If pre-Change documents are sent after implementation of the change, the associated documentation will reflect the pre-Change status, as these are issued at the time of batch release.

Our Change Notification letters are always approved by Quality, as Change Notification Letters are Quality documents and controlled by the Quality Organization.

Related Contract(s)

For a more convenient overview we give a table with Contract ID, Customer Name and Customer Address of the Change Notification Commitment or Quality Agreement which is the basis for the Change Notification.



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