

Change control notification

Reference : CN2017-53 – Issue date : 23-AUG-2017

Subject: Label intended use and statement on Certificate Of Analysis change for Lonza liquid standard products.

Indication of the country of origin on the product label.

Dear valued Customer,

In compliance with our Change Notification procedure, we would like to submit the following change.

1- Change description:

This change notification is intended to inform you about the modification of the intended use on the product label, and accordingly the update of the statement on the Certificate Of Analysis (COA) for some of Lonza products part codes.

Lonza Verviers decided to clarify and to harmonize the intended use claimed on the label of the Lonza liquid standard products.

The intended use is related to the Lonza product category as follow:

Lonza product category	Intended use
Lonza products manufactured under ISO 9001 standards.	For Research Use Only. Not for use in diagnostic procedures.
Lonza products manufactured under cGMP 21 CFR 820 Quality System Regulation.	For Further Manufacturing or Laboratory Use.

In addition to this change on the product label, the statement included in the Lonza liquid standard products COA has been updated in our ERP system to be aligned and compliant with the claimed intended use.

In parallel to this change, the mention "Made in Belgium" has been also added on the product label.

Lonza Verviers S.p.r.l.

Parc Industriel de Petit-Rechain, B-4800 Verviers, Belgium - Tel : + 32 (0) 87 32.16.11 Fax : + 32 (0) 87 35.19.67

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2- Reason of the change:

Lonza Verviers wants to clarify and harmonize the intended use of the Lonza liquid standard products. The change also assures that the product label claim is compliant with the intended use of the product.

The "Made in Belgium" mention has been added in order to comply with the US Customs Regulations CFR Title 19, Part 134 requiring that products imported to the US must be properly marked with the country(ies) of origin in the English language.

3- Change implementation:

The change is immediately implemented for any new order of a Lonza standard product and for any products remaining at Lonza stock.

The change is only an administrative change and does not impact the product quality. Therefore, no specific action has to be taken on the batches already released and distributed. However for these batches, there might be a discrepancy between the labels and the COA as, due to our ERP system, any new edition of a COA of an already released batch will automatically include the updated statement.

4 – Products concerned by the change:

All Lonza liquid standard products are impacted.

5- Criticality of the change:

We consider the change as minor for the following reasons:

- The change is only an administrative change with no impact on the product quality.
- The change is an improvement in terms of clarification/harmonization and compliance (product label claim in accordance with the product intended use and compliance to the US Customs Regulations).
- The manufacturing process of the products remains exactly the same.

Please contact Lonza Verviers Customer Service at +32 (0) 87 32 16 11 or Lonza Technical Support if you need additional information on this change notification.

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Audrey WILLEMS
QA Professional
Lonza Verviers SPRL

Lonza Verviers S.p.r.l.

Parc Industriel de Petit-Rechain, B-4800 Verviers, Belgium - Tel: + 32 (0) 87 32.16.11 Fax : + 32 (0) 87 35.19.67

List of Part-numbers impacted by Change Notification CN2017-53:

51217	BE02-037F	BE10-543F
51219	BE02-038P0.5	BE10-547F
51225	BE02-038P20	BE12-029Q
51226	BE02-038P200	BE12-105F
51217	BE02-039Q	BE12-109F
51219	BE02-040E	BE12-115F
51225	BE02-041Q	BE12-115F/U1
51226	BE02-042Q	BE12-117F
AGM-100M	BE02-043E	BE12-118F
AGM-500M	BE02-044Q	BE12-119F
BE02-002F	BE02-044Q	BE12-125F
BE02-007E	BE02-052Q	BE12-125Q
BE02-011F	BE02-053Q	BE12-127F
BE02-012E	BE02-054Q	BE12-136F
BE02-014F	BE02-055Q	BE12-136Q
BE02-015BOX	BE02-056Q	BE12-167F
BE02-015E	BE02-058E	BE12-168F
BE02-015F	BE02-059E	BE12-169F
BE02-015X5	BE02-059F	BE12-604F
BE02-016Q	BE02-059Q	BE12-604F/U1
BE02-017F	BE02-060F	BE12-604Q
BE02-019F	BE02-060Q	BE12-611F
BE02-025Q	BE02-061Q	BE12-611Q
BE02-026E	BE04-380Q	BE12-614F
BE02-026F	BE04-448Q	BE12-614Q
BE02-027F	BE04-558F	BE12-615F
BE02-028Q	BE04-684E	BE12-618F
BE02-029Q	BE04-687F/U1	BE12-662F
BE02-030Q	BE04-687Q	BE12-668F
BE02-032Q	BE04-719Q	BE12-684F
BE02-033E	BE04-743Q	BE12-688F
BE02-033E20	BE06-174G	BE12-700F
BE02-033E80	BE08-238Z10	BE12-702F
BE02-033F400	BE08-238Z10	BE12-702F/U1
BE02-033Q	BE08-238Z4	BE12-702Q
BE02-034E	BE08-238Z4	BE12-707F
BE02-035E	BE10-502F	BE12-708F
BE02-035F	BE10-508F	BE12-709F
BE02-036F	BE10-527F	BE12-719F

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BE12-719Q	BE17-513F	BEBP02-054Q
BE12-722F	BE17-513Q	BEBP02-055Q
BE12-723F	BE17-515F	BEBP02-060F
BE12-725F	BE17-515Q	BEBP02-060Q
BE12-726F	BE17-516F	BEBP02-061Q
BE12-730F	BE17-516Q	BEBP04-380Q
BE12-730P10	BE17-517Q	BEBP04-448Q
BE12-730Q	BE17-524CM	BEBP04-743Q
BE12-733F	BE17-524QM	BEBP04-744Q
BE12-739F	BE17-524ZM	BEBP12-029Q
BE12-741F	BE17-605E	BEBP12-684F
BE12-743F	BE17-605E/U1	BEBP12-725F
BE12-749Q	BE17-605F	BEBP12-730F
BE12-752F	BE17-613E	BEBP12-730Q
BE12-756EM	BE17-711E	BEBP12-743F
BE12-756FM	BE17-724F	BEBP12-749Q
BE12-761F	BE17-724Q	BEBP12-764Q
BE12-764Q	BE17-737E	BEBP12-766Q
BE12-766P10	BE17-829E	BEBP12-771Q
BE12-766P20	BE17-829F	BEBP12-776Q
BE12-766Q	BE17-855E	BEBP12-917F
BE12-771P10	BE344017	BEBP17-605E
BE12-771P20	BE50843	BEBP17-855E
BE12-771Q	BE50843	BECB002L200/150
BE12-914F	BE50879	BECB002L200/150
BE12-915F	BE50879	BECB003P5/3.7
BE12-917F	BE51200	BEEL08-11R
BE12-918F	BE51200	ECB2000L
BE12-927Q	BE51205	ECB2071L
BE13-114E	BE51205	ECB2072L
BE13-115E	BE51232	ECB3000D
BE13-668C	BE51232	ECB4004L
BE13-668F	BE51233	ECB4053L
BE13-668F+A	BE51233	ECB7501L
BE13-668F280	BEBP02-016Q	ECB9006D
BE13-668F350	BEBP02-025Q	ECB9006L
BE13-668Z	BEBP02-028Q	ECM0019L
BE13-708Q	BEBP02-029Q	ECM0103L
BE17-160E	BEBP02-030Q	ECM0495L
BE17-161E	BEBP02-032Q	ECM0728L
BE17-161F	BEBP02-041Q	ECM0749L
BE17-512F	BEBP02-042Q	EKAMM100
BE17-512Q	BEBP02-053Q	

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