



Urgent Field Safety Notice

XX May 2018

Notification Number: CN-71935571-2 (2nd Notification)

The purpose of this Field Safety notice is to inform you of an issue impacting product purchased by your company. A copy of this letter should be forwarded immediately to the personnel in your organization that utilize this product.

Affected Product(s)

Item No.	Item Description	Lot / Batch
9031	Minicon BS15	See Table 2
9051	Minicon CS15	See Table 2

Description of the Issue

This Field Safety notice relates to a recent internal investigation highlighting that you may observe increased concentration times of greater than the specification of 3 hours and up to 24 hours for devices used greater than 6 months after date of manufacture.

Reason for the Notification

Minicon devices are registered in the USA, Europe, Australia and Canada for In Vitro Diagnostic Use and are intended to concentrate urine and cerebrospinal fluid or other biological solutions. The potential impact of this issue will be prolonged time of up to 24 hours required to concentrate a sample which may lead to delays in carrying out the subsequent analysis tests.

Corrective Action

Following the investigation results, the shelf life for these Minicon devices has been reduced from 12 months to 6 months.

Merck KGaA, Darmstadt, Germany
Corporation with General Partners
Frankfurter Str. 250
64293 Darmstadt, Germany
Phone +49 6151 72-0

Sigma-Aldrich Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
3050 Spruce Street
St. Louis, MO 63103, USA
Phone +1 (800) 521-8956 +1 (314) 771-5765

EMD Millipore Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
400 Summit Drive
Burlington, MA 01803, USA
Phone +1 (781) 533-6000

Required/Recommended Action

Please immediately examine your inventory to determine if you have any remaining impacted product and forward a copy of this letter to the personnel in your organization that utilize this product and/or need to be made aware of this issue.

In addition, if you have further distributed this product, please identify your customers and notify them at once of this issue. Your notification to customers should include a copy of this notification and Attachment 2.

Please stop use of these lots if older than 6 months and destroy any remaining inventory older than 6 months.

Please complete and return the receipt confirmation form in Attachment 1 to QACorkGroup@merckgroup.com.

Additional Information

We have informed our competent authority and competent authority in countries where the product has been distributed of this Field Safety Notice

Attachments

Table 1: Western - European local representative contact details

Table 2: Lot numbers

Attachment 1: Confirmation of receipt of Notification

Attachment 2: Confirmation of receipt of Notification (Distributor use only)

This notification has been evaluated and approved by representatives from Quality and Product Management.

If you would like more information regarding this notification, please contact us at QACorkGroup@merckgroup.com or go to our website to find the phone number of your local office at www.emdmillipore.com/offices.

We apologize for any inconvenience that this issue may cause you. Thank you for your loyal business.

Merck KGaA, Darmstadt, Germany
Corporation with General Partners
Frankfurter Str. 250
64293 Darmstadt, Germany
Phone +49 6151 72-0

Sigma-Aldrich Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
3050 Spruce Street
St. Louis, MO 63103, USA
Phone +1 (800) 521-8956 +1 (314) 771-5765

EMD Millipore Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
400 Summit Drive
Burlington, MA 01803, USA
Phone +1 (781) 533-6000

Table 1: Western - European local representative contact details

Area	Language	Email address
DE/AT/CH	German	technischerservice@merckgroup.co
CH	Italian	serviziotecnico@merckgroup.com
CH	French	servicetechnique@merckgroup.com
FR/BE/CH	French	servicetechnique@merckgroup.com
BE/NL	Dutch	technischeservicebenelux@merckgroup
UK/IR/Nordics	English	TechnicalService@merckgroup.com
SP/PT	Spanish	serviziotecnico@merckgroup.com
IT	Italian	serviziotecnico@merckgroup.com

Merck KGaA, Darmstadt, Germany
Corporation with General Partners
Frankfurter Str. 250
64293 Darmstadt, Germany
Phone +49 6151 72-0

Sigma-Aldrich Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
3050 Spruce Street
St. Louis, MO 63103, USA
Phone +1 (800) 521-8956 +1 (314) 771-5765

EMD Millipore Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
400 Summit Drive
Burlington, MA 01803, USA
Phone +1 (781) 533-6000

Table 2: Lot numbers

Catalogue Code	Lot Number
9031	R7HA21782
	R7HA25141
	R7HA25142
	R7HA25143
	R7JA25144
	R7JA29966
	R7KA29967
	R7KA37204
	R7KA47996
	R7KA47998
	R7MA62669
	R7MA62670
	R7MA62671
	R7MA70413
	R7MA73041
	R7NA73042
	R7NA76185
	R7NA76186
	R7NA84720
	R7PA90587
	R7PA90588
	R7SA03064
	R8AA13174
	R8AA13175
	R8AA13176
	R8AA17729
9051	R7HA32882
	R7HA33739
	R7HA33741
	R7MA53165
	R7MA53166
	R8AA13177

Merck KGaA, Darmstadt, Germany
 Corporation with General Partners
 Frankfurter Str. 250
 64293 Darmstadt, Germany
 Phone +49 6151 72-0

Sigma-Aldrich Corporation
 A subsidiary of Merck KGaA, Darmstadt, Germany
 3050 Spruce Street
 St. Louis, MO 63103, USA
 Phone +1 (800) 521-8956 +1 (314) 771-5765

EMD Millipore Corporation
 A subsidiary of Merck KGaA, Darmstadt, Germany
 400 Summit Drive
 Burlington, MA 01803, USA
 Phone +1 (781) 533-6000

**Attachment 1: Confirmation of receipt of Notification
Minicon – Urgent Field Safety Notice CN-71935571-2**

Company Name (Block Capitals): _____

I/We Confirm receipt of the above-mentioned notification

Name (Block Capitals): _____

Position: _____

Email address (for follow-up contact): _____

Signature: _____

Date: _____

Please return to QACorkGroup@merckgroup.com

Merck KGaA, Darmstadt, Germany
Corporation with General Partners
Frankfurter Str. 250
64293 Darmstadt, Germany
Phone +49 6151 72-0

Sigma-Aldrich Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
3050 Spruce Street
St. Louis, MO 63103, USA
Phone +1 (800) 521-8956 +1 (314) 771-5765

EMD Millipore Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
400 Summit Drive
Burlington, MA 01803, USA
Phone +1 (781) 533-6000

Attachment 2: Confirmation of receipt of Notification (Distributor use only)
Minicon –Urgent Field Safety Notice CN-71935571-2

Company Name (Block Capitals): _____

I/We Confirm receipt of the above-mentioned notification

Name (Block Capitals): _____

Position: _____

Email address (for follow-up contact): _____

Signature: _____

Date: _____

Completed attachment to be returned to distributor

Merck KGaA, Darmstadt, Germany
Corporation with General Partners
Frankfurter Str. 250
64293 Darmstadt, Germany
Phone +49 6151 72-0

Sigma-Aldrich Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
3050 Spruce Street
St. Louis, MO 63103, USA
Phone +1 (800) 521-8956 +1 (314) 771-5765

EMD Millipore Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
400 Summit Drive
Burlington, MA 01803, USA
Phone +1 (781) 533-6000