

Mechatronics Instruments B.V.

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April 4th, 2023

**Medical Device Field Safety Field corrective action:
QRR049001 Starrsed Control Level N and QRR049002 Starrsed Control Level A**

Dear ????????,

RR Mechatronics is requesting you to perform a Medical Device Field safety corrective action for the abovementioned RR Mechatronics articles. We are contacting you as the affected product may have been supplied to your organization.

Intended use

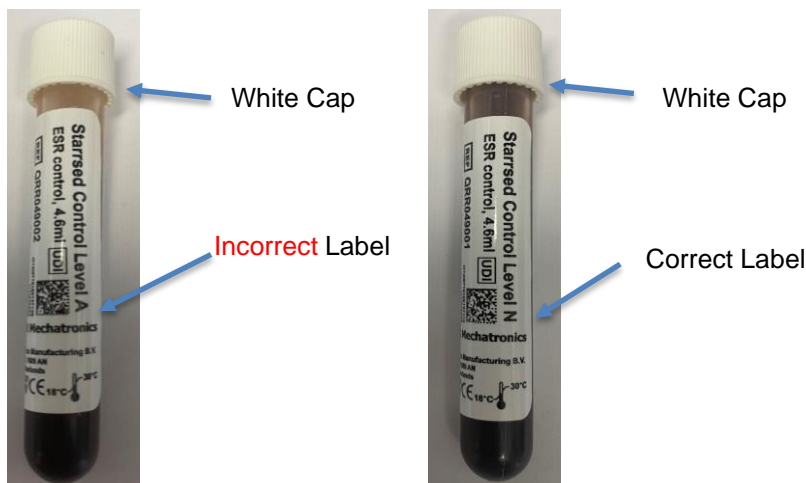
For in vitro diagnostic use. Quality control material to monitor the precision of Starrsed Erythrocyte Sedimentation Rates (ESR) instruments and procedures.

Description of the issue

It has been brought to our attention that there is a small amount of vials of QRR049001 Lot QCAB6AN505 incorrectly labelled as QRR049002 Lot QCAB6AAA28. Investigation has shown no other RR Mechatronics devices are involved.

Example

QRR049001 – Starrsed Control Level N can be identified by the colour of the cap (White Cap)



For Starrsed instruments that are currently in use, using the Control barcode feature the assigned ranges are automatically uploaded to the instrument from the barcode on the vial. The incorrectly labelled vial will upload the range for the Starrsed Control Level A and the instrument result will be flagged as out of range. Once you notice this issue, please check the label on the vial and if incorrectly labelled perform a rerun using a correctly labelled vial.

Table 1. Affected Product and Batch/Lot Number

Product name	Product code	Batch/Lot Number	QTY delivered
QRR049001 – Starrsed Control Level N	QRR049001	QCAB6AN505	TBD
QRR049002 – Starrsed Control Level A	QRR049002	QCAB6AAA28	TBD

Quantities delivered:

Field Safety Field corrective action to be taken by the customer:

1. Confirm that you have received this information by returning enclosed acknowledgement form.
2. Please check your inventory for QRR049001-Starrsed Control Level N-Lot QCAB6AN505.
3. Please check your inventory for QRR049002-Starrsed Control Level A-Lot QCAB6AAA28.
4. Confirm the date and number of unused incorrectly labeled vials in your inventory.
5. Discard any unused incorrectly labelled vials in your inventory.
6. Please indicate the number of requested replacement vials.

Please document the information on the enclosed Return Form and send to marjon.wagter@rrmechatronics.com

Transmission of this notice

We kindly ask you to inform those who need to be aware of this notification within your organization or any other organization to which the affected product(s) have been transferred. We need confirmation of the complete delivery of this lot. By completing the above mentioned enclosed Return Form by yourself and affected customers.

Please ensure that your organization maintains awareness of this notice.

Thank you for your attention to this matter. We apologize for any inconvenience that this action may cause, and we appreciate your understanding as we take action to ensure customer satisfaction.

Yours sincerely,

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