

[NAME] [ADDRESS 1] [ADDRESS 2]

Urgent SAFETY NOTICE

Scewo AG, Switzerland

Affected products:

- Scewo BRO V1
- Scewo BRO V1.1 (Basic UDI-DI: 7649992967BRWF)

Date: [Date] Ref. FSCA-42

Type of action: retrofit of the device Scewo BRO

Dear [NAME],

Here at Scewo we take the safety of our users as the top priority. We continuously monitor our internal processes and our products on the market and we strive to constantly improve our product quality to ensure your safety in every aspect. We do this in particular to ensure the safety of our customers in every respect and in all situations.

We received feedback from one of our users that a wheel got loose from its axle. Fortunately, the user did not get injured but we are taking this event very seriously.

Engineers, technicians and product specialists immediately investigated the cause of this incident and based on the information we gathered, we identified a potential safety risk around the axle of the wheel of BRO. Even though such a situation was evaluated to be of low probability, a loss of the wheel could result in a serious injury. Therefore, we decided to undertake a Field Safety Corrective Action.

Scewo has developed a retrofittable solution. This solution adds a secondary barrier against loosing of the wheel so that BRO can be used safely without any further occurrence of such an event. The solution is available as of today.

With this letter, we would like to inform you that all necessary steps have already been taken. At the same time we ask for your support to implement these safety corrective measures.



Details on affected devices:

All BROs on the market are potentially affected. Therefore all BROs will be inspected and reworked by a technical expert from Scewo AG or by our official partners. This will be provided free of charge to our customers.

Action to be taken:

- (1) **[User and Partner]** Acknowledge this letter by writing an email to tech-support@scewo.ch with Ref: FSCA-42 in the subject or use the follow up response in page 4 and return it to Scewo AG.
- (2) **[User and Partner]** In case you notice an abnormal behavior/sound especially in regards to the drivetrain or wheel, stop immediately using the device until it gets retrofitted.
- (3) **[Scewo]** The shaft of the BRO needs to be secured with an additional piece as soon as possible but not later than 4 months after receipt of this notice.
- (4) **[User]** We recommend you to contact Scewo to schedule this retrofit of your BRO. This can be combined with the action (1).
- (5) **[Scewo]** Once the retrofit is done, Scewo informs Partners about the completion of the actions.

Distribution of the information described in this Field Safety Notice:

Please transfer this notice to **your organization or all other organizations** which can be impacted by this field safety notice.

Please pass this notice on to all who need to be aware and where the potentially affected devices have been transferred.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The relevant National Competent Authorities have been informed via a FSCA (i.e. Field Safety Corrective Actions).



Contact:

If you have any questions relating to this notice, or should you require any additional information, please contact:

<u>Customer Service at Scewo AG:</u>

Tel: +41 44 500 86 03

Email: tech-support@scewo.ch

We apologize for any inconveniences caused by this field safety notice.

Pascal Buholzer
Co-Founder & CTO



- Reply form -

It is important that you confirm that you have received this Field Safety Notice.

☐ I have read and understood this Field Safety Notice.	
☐ I confirm that I have distributed this Field Safety Notice to the affected user(s).	
Name:	
Address:	
Date:	
Signature:	

Please return this page once completed to this address:

Scewo AG Technoparkstrasse 7 8406 Winterthur Switzerland

You can also write us an email to <u>tech-support@scewo.ch</u> with Ref: *FSCA-42* in the subject and acknowledge the reception of the Field Safety Notice. Please right the following:

"I have read and understood this Field Safety Notice and I confirm that I have distributed it to the user(s)"