

[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: 14. January 2023

Ref. FSCA-42

Type of action: retrofit of the device

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 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.

We 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 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.
- (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. Scewo will provide to the Partners the instructions and material kit for the retrofit in a separate letter. Please note that only authorized personnel (ie. Scewo members and Partners) are allowed to retrofit the BRO.
- (4) **[User]** We recommend you to contact Scewo or one of our official Partners to schedule this retrofit of your BRO. This can be combined with action (1).
- (5) **[Partner]** Once the retrofit is done, inform Scewo 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.



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