

Quality form - FQ.8.2.3.010.

„Reporting to government authorities“



Activity:

FSN (Field Safety Notice) "Safety information, notification, feedback and safety information to the user to prevent possible risks.

Scope of application:

AGA, dealers, users

Versions-no.: 00

					Employee
Created by:		Released by:		Changed by	
Date:	08.06.2018	Date	25.10.2018	Date	

AGA Sanitätsartikel GmbH

Telephon:

Fax:

E-Mail:



Löhne, 28.05.2025

Urgent safety information for
(examination unit & examination couch),
Order no.: BUD-6265, ELI-8000, ELI-8020,
PRAX-6000, ULI-6000, ULI-6020, ULI-6030,
Production from 04/02/2025 - 14/05/2025)

Description of the problem including the identified cause:

A weld seam on the retaining plate was not sufficiently welded.

Risk:

Weld seams could come undone and the structure of the upholstered frame of the couch in question would give way.

What measures are to be taken by the addressee?

The examination tables with the above order numbers, which were manufactured between 04/02/2025 and 14/05/2025, must be blocked immediately.

The type plate of the examination table is located on the inside of the frame towards the head end. Please see a corresponding example.



The date of manufacture can be read to the right of the (11) in YY.MM.DD, in the example (in the ellipse) therefore 20 May 2025. The order number can also be seen on the type plate. In the example to the right of type (in the rectangle) **ELI-8000**.

The four support legs with the welded-on safety plates must be replaced with the support legs without safety plates. Please also refer to the installation instructions DE.0191. The examination table is then in a safe condition again and can be used as usual.

FQ.8.2.3.0.10.

Passing on the information described here:

In your organisation, please ensure that all users of the examination table mentioned above and other persons to be informed are made aware of this urgent safety information. If you have given the examination couch to third parties, please be sure to forward a copy of this information or inform the contact persons listed below.

The Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this 'Urgent Safety Information'.

Contact person:

[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]

Löhne, 28.05.2025

[Redacted]
[Redacted]

[Redacted]
[Redacted]

REPLY FORM

IMPORTANT NOTE ON SAFETY-RELEVANT CORRECTIVE ACTION

Order no.: BUD-6265, ELI-8000, ELI-8020, PRAX-6000, ULI-6000, ULI-6020,
ULI-6030

FSCA identifier: 21580/25 (BfArM case number)

Date: 28.05.2025

Type of measure: ULI-KIT for retrofitting.

Instructions:

1. you will automatically receive the 'ULI-KIT' for replacing the legs in the next few days.
2. please fill in this reply form **after replacing** the reclining legs and send it back to us.

By completing this reply form, you confirm that you have read and understood the above information regarding the safety instructions and that the measure (replacement of the reclining legs) has been carried out.

Serialnumber (SN - is located at the bottom left of the rating plate): _____

Name of the organisation _____

Name of contact person in block letters: _____

The table legs were replaced on, date: ____/____/____

Signature (and stamp if available): _____

Telephon: _____ EMail: _____

Please complete and return by e-mail or fax to:

AGA Sanitätsartikel GmbH
Löhner Straße 198b
D-32584 Löhne

E-Mail: info@agasan.com **Fax:** +49 (0)5731 81976

Please only choose the postal route if the other two options are not available to you.