

Formblatt

8.2.3 Safety Information

FSN – FIELD SAFETY NOTES

Type of measure (e.g. recall, field safety note, preventive action)

SAFETY INFORMATION

Trade name of the affected medical devices

proSA Valve and proSA Shuntsystem

Potsdam, the

Sender

Christoph Miethke GmbH & Co.KG
Ulanenweg 2
14469 Potsdam

Recipient

- ☐ patients
- ☐ user
- ☐ operator
- ☐ distributor

Description of the non-conformity including root cause analysis

We recommend strongly to execute the following actions.

FSN – FIELD SAFETY NOTES*Type of measure (e.g. recall, field safety note, preventive action)***SAFETY INFORMATION***Trade name of the affected medical devices****proSA Valve and proSA Shuntsystem*****Passing on the information described**

Please make sure that all users of the above obtained products and other relevant persons of your organization are aware of this **Field Safety Notice**. If you have passed the products of third parties, please forward a copy of this information or inform the contact person listed below.

Please keep this information at least until the action has been completed.

The „BfArM“ has received a copy of this **Field Safety Notice**.

Contact Person

If you have any queries, please contact the contact persons listed below.

Company:

Contact person:

Position:

Tel.:

Fax:

E-Mail:

Recall of devices, please forward the return of products to the following address.

Company:

Contact person:

Position:

Street | No.

Zip | place

Receipt of acknowledgement**Notice**

We hereby acknowledge the receipt of the **Field Safety Notice**. We ensure that all users of the above obtained products and other relevant persons in our organization are aware of this **Field Safety Notice**. If the products were submitted to third parties, we will forward a copy of this information or inform the company Christoph Miethke GmbH & Co. KG

Implementation of recommended actions

We confirm, that we will carry out or have carried out the previously described and strongly recommended actions.

place, date

Name of receiver

Stamp | signature**Return of acknowledgement of receipt**

Company:

Contact person:

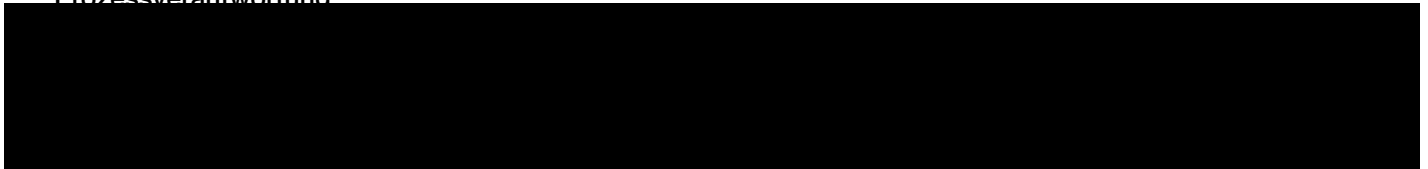
Position:

Tel.:

Fax:

E-Mail:

Prozessverantwortung



Anderungshistorie

Version	Änderungsbeschreibung	Schulung?
1	Anpassung Kapitel entsprechend EN ISO 13485:2016	Ja
2	Neues Firmenlogo eingefügt, mitgeltende Dokumente angepasst PV geändert von F. Ahrendt zu J. Meusch	Nein

Glossar

Abkürzung	Beschreibung
FSCA	Field Safety Corrective Action
QM	Qualitätsmanagement

Mitgeltende Dokumente

Dokument Nr.
LI 3.0 Abkürzungen
LI 4.2 Aufbewahrungsfristen
AA 4.2.1 Gute Dokumentationspraxis
UP 8.2.3 Berichterstattung Regulierungsbehörden