

Meta-Information

Document	FB 063 Field Safety and Advisory Notice.pages	Author	AVO
Version	1.00	Date	23.11.2020

Document Approval

Name	Function	Date	Signature
Jens-Christian Frohwitter	CEO	23.11.2020	
Axel Voss	COO	23.11.2020	

*) Format: YYYY-MM-DD

**) Status: Draft, approved

Content**Document History**

Version	Date*)	Author	Status**)	Description
V1.00	2020-Nov-23	AVO	Approved	Initial creation

1. Scope

This document will be used as a template for a Field Safety Notice or Advisory Notice. For examples of FSNA and National Competent Authority Report Form please refer to MEDDEV 2.12-1 rev 6.

SOP 005 needs to be applied for filing.

Urgent Field Safety / Advisory Notice

Commercial name of the affected product, FSCA-identifier:
curason CSN 01 ultrasonic wound cleaner

Type of action (e.g. chapter 4 definition of a FSCA):
discontinuation of use of the devices

Date: 25.04.2025

Attention: TO WHOM IT MAY CONCERN

Specific details to enable the affected product to be easily identified:

Details on affected devices:	All devices installed in the Slovenian market
Type of device:	ultraasonic wound cleaner
Model name:	curason
Model number:	CSN 01
Lot Numbers of affected devices:	All devices installed in the Italian & Slovenian market
Serial numbers of affected devices:	See list attached
Part or order numbers:	-

Description of the problem:

The Competent Authority "Landesamt für Soziale Dienste" in Schleswig-Holstein, Germany, has identified non-conformities in the technical documentation of the curason that might lead to safety issues when being used. The devices shall be put out of order.

Advise on action to be taken by the user:

- please identify all devices being installed at your facilities and put them into out of order by not making them available to your personnel*

Contact reference person:	
Name	Axel Voss
Organisation/Company	curasonix GmbH
Address	Lübecker Str. 42, 23611 Bad Schwartau, Germany
Contact details	

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

Date: **April 25th 2025**

Reviewer: **Axel Voss**

Signature: