Urgent Field Safety Notice

ARS Decompression Needle
FSCA- 22 September 2017
Type of action FSCA

Date: 27 September 2017

Attention: Distributor

Details on affected devices:
North American Rescue has determined that the ARS Decompression Needles were shipped with two CE Notified Body Numbers. Please see product description below in figure 1 and impacted part numbers and lots in figure 2.

Figure 1

35 Tedwall Court ● Greer, South Carolina 29650-4791
Office: (864) 675-9800 ● Fax (864) 675-9880 ● Toll Free: (888) 689-6277
www.NARescue.com

Product #	Lot #
ZZ-0056	S703SG
ZZ-0298	T156WA
ZZ-0056	S688SA
ZZ-0056	S704WA
ZZ-0298	S970PH
ZZ-0056	S705YP
ZZ-0056	T425BJ
ZZ-0056	T413CM
ZZ-0056	T414FF
ZZ-0298	T341ZJ
ZZ-0056	T415GP
ZZ-0056	T669JF
ZZ-0056	T670LD

Figure 2

Description of the problem:
Device was shipped with CE # 0086 (BSI) number after the certificate expired and CE # 0050 (NSAI) prior to issuance. The device was approved by NSI under certificate 252.01116. The firm has received no reports of any safety concerns on device application and the risk management file remains active, with no update warranted.

Advise on action to be taken by the user:
Please quarantine and return for replacement all product identified in Figure 2.
There is no safety or efficacy impact to casualty or clinician.

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organization.

Contact reference person:

William Slevin
Director, QA/RA
North American Rescue, LLC
wslevin@narescue.cpm
fax: 001 -864-675-9880

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

Signature

Completed by: [redacted] Date: September 27, 2017

William Slevin

Director, QA/RA