

Urgent Field Safety Notice

Emergency Trauma Dressing and Gauze
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 Emergency Trauma Dressing and Gauze 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



Product #	Lot #
30-0052	2116
30-0012	4316
30-0031	4516
30-0165	2516
30-0031	4916
30-0031	4716
30-0012	0217
30-0012	0517
30-0031	5116
30-0052	3116
30-0012	2217
30-0052	5016
30-0052	0171

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

Signature

Completed by: 

Date: September 27, 2017

William Slevin
Director, QA/RA