Urgent Field Safety Notice

Commercial name of the affected product	ECO BATH WIPES with 2% w/v Chlorhexidine Gluconate Solution Product Code : CMPL22
FSCA-identifier	CMPL-FSCA-JUN2018
Type of action	The return of a MEDICAL DEVICE to the supplier
Date	30 June 2018

Attention

Details on affected devices:

- Device Name : ECO Bath Wipes of 10 pcs with 2% w/v Of Chlorhexidine Gluconate Solution
- Product Code: CMPL22
- Batch Number: EP004
- Manufacturing Date: 2018-03-26
- Expiry Date: 2018-03-25

Manufacturer
CareNow Medical Pvt Ltd, #3/272-5 Neelambur Road, Muthugoundenpudur, Coimbatore, India-641406.Ph: +91 422 2914949, E: info@carenowindia.com, W: www.carenowindia.com

Description of the problem

ECO Bath Wipes contain an active ingredient Chlorhexidine Gluconate Solution at 2%w/v (Equivalent to 0.5% w/v of Chlorhexidine Gluconate Salt). The product is used for Cleaning, moisturizing and protecting patients at hospitals.

The responsible local Competent Authority DE/CA70, Landesamt für Umwelt- und Arbeitsschutz, Saarbrücken/Germany has received a COEN notification from an European Competent Authority in regard to the classified as Class I products. However due to the use of the Chlorhexidine, the products would be Medical Devices under Class III, Rule 13 of Annex IX Mdd93/42/EEC.

As no conformity evaluation procedure related to the Class III product was performed and no CE-certificate issued by a Notified Body is available, the marketing of the products have to be stopped.

. Until, the product is reclassified the product cannot be marketed further from this date of notification.

- FSCA is initiated because the device classification of Class 1 MDD no longer applies to ECO Bath with 2% w/v of CHG Solution and the product not marketed anymore in the European Region.

Deficiency

- The product not correctly placed on the European Market

Risk Analysis

- Risk analysis conducted for the product does not indicate any hazard to patient on previous usage of the product.
- No risk is identified with previous use of the device.
- However the FSCA is initiated due to the presence of Chlorhexidine

Corrective/Preventive Action by User

- Any product in the market should not be used on the patient further and the product should be returned to the Distributor in the region.

Corrective Action by Manufacturer

- Subject to the changes in regulations, Manufacturer will determine the current classification of the product with documentation and apply for certification process with Notified Body.
- Device will not be marketed as Class 1 MDD from the date of this notice.

Advise on action to be taken by the user:

- Any product in the market should not be used on the patient further and the product should be returned to the Distributor in the region.

Transmission of this Field Safety Notice

This notice is sent to the Distributors in EU and the concerned customers.

Local contact point:

[redacted]

Contact reference person of the manufacturer:
Mr.Arunkumar
Quality Manager, CareNow Medical Pvt Ltd, , #3/272-5 Neelambur Road, Muthugoundenpudur, Coimbatore, India- 641406

The undersign confirms that this notice has been notified the appropriate national competent authority.

Signature