

Orvieto, March 13th 2017

Urgent – Product Recall 1st notification – Urgent

Recall Product Notification

Product Part #	Description	Lot #
95600	Easyderm wipes	W16160NA

This letter is to inform you of a voluntary recall from Welcare Industries Spa for our Easyderm wipes

The recall, requested by our Ministry of Health, is due to a potential contamination by *Burkholderia cepacia*.

Welcare Industries undergoes the recall as a precaution but declares the following:

- No incident related to Easyderm wipes has. Ever been reported by a European or non European country
- The device, non sterile, conforms to the Europea Pharmacopeia, that requests the eventual presence of environmental bacteria to be below 200CFU/gr
- The type of bacteria eventually present in the device would be *Burkholderia cepacia stabilis* that, although involved in nosocomial infections as many other common environmental bacteria, is proven to raise opportunistic infections less frequently than other types. (*Vasiljevi et al. 2016; Wang et al. 2015, Barrda et al. 2013; Correa Ruiz et al 2013; Lambiase A: 2013; Heo et al 2008, Leitao et al. 2008, Bash et al 2008; Boussaud et al 2008, Otag et al. 2008*)

Potential Risk .

We repeat that the risk is minimal because:

- No incidents have ever been reported
- The product conforms to the European Pharmacopeia
- The risk represented by the type of bacteria is minimal

Actions for Customers:

- Please inspect your inventory, locate the lot identified in the above table and quarantine it immediately
- Complete the form below indicating the quantities that need to be returned. If you do not have product to return, please place an "X" in the column "No Product to Return"
- Forward this document, complete with your specific contact information, to info@welcaremedical.com
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Actions for the Distributor

Send this letter to your customers and ask them to return the recalled product. You may translate the letter if necessary

Product Part #	Description	Lot #	Individual Units to be returned	No product to return
95600	Easyderm wipes	W16160NA		

Completed by

Name

Signature

Hospital/Company

Address

Telephone number

Date

Fax

Please return this form to info@welcaremedical.com.