

## Urgent Field Safety Notice Covidien DAR™ airway products Recall

June 2021

Medtronic reference: FA975 phase II

Dear Customer,

As a follow-up to the Urgent Field Safety Notice Medtronic issued in April 2021, Medtronic is now issuing a market withdrawal in the European Economic Area (EEA) for specific production lots of its Covidien DAR™ airway products.

### Issue Description:

Medtronic has concluded its investigation of potential deviations in the ethylene oxide sterilization processes performed by Steril Milano, the former supplier of our sterilization services for the DAR™ airway products. Medtronic analyzed the available sterilization data and conducted validation tests on production lots where data was available. Our analysis concluded there was no quality issues for production lots where data was available. Where data was not available for our investigation, we have concluded that those specific production lots will be voluntarily recalled.

The withdrawal and recall actions affect item codes and lot numbers under quarantine at customer facilities in the EEA+CH+TR+UK as per April 2021 Medtronic communication. The products being withdrawn have no identified quality issues. Medtronic continues to work with our notified body and competent authorities in the EEA+CH+TR+UK to review the results of our investigation and analysis of the lots being withdrawn from the EEA+CH+TR+UK market.

Customers in the EEA +CH+TR+UK are requested to return all product currently under quarantine.

### Required Actions:

1. Please immediately return to Medtronic all remaining product currently quarantined as a result of the April 2021 Urgent Field Safety Notice.
2. All unused products from the affected item codes and lots must be returned.
3. If you have distributed the DAR™ airway products, please promptly forward the information from this letter to those recipients.

### Additional Information:

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions, please contact your Medtronic Representative at 01 511 1400.

Sincerely,



Samantha Baxter  
Regulatory Affairs Manager  
UK and Ireland

Identifying Affected Product

Item code

Lot number

**COVIDIEN** positive results for life™  
**DAR™**  
 Adult-Pediatric Electrostatic Filter HME  
 Small  
 Vt 150-1200 mL

REF 352/5877Z  
 LOT XXXXXXXXX  
 Use-by YYYY-MM-DD

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**DAR™**  
 Adult-Pediatric Electrostatic Filter HME  
 Small  
 Vt 150-1200 mL

REF 352/5877Z  
 LOT XXXXXXXXX  
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25

GTIN - FPO (01)20894 521077406  
 EXP/LOT - FPO 17YYMMDD(10)XXXXXXXXXXXX

STERILE EO  
 Not made with natural rubber latex  
 Single use  
 Rx ONLY  
 Not made with DEHP  
 Caution, consult accompanying documents  
 CE 0123

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