

# Central Drugs Standard Control Organization

Directorate General of Health Services  
Ministry of Health and Family Welfare  
Government of India  
(Medical Devices and Diagnostics Division)

Food & Drugs Administration Bhavan,  
Kotla Road, New Delhi.

File No: 31-1488-MD/2014-DC

Date:

## MEDICAL DEVICE ALERT

13 APR 2017

### DEVICE

3M Tegaderm Film Transparent Film Dressing Frame Style

### BACKGROUND

3M Tegaderm Film Transparent Film Dressing Frame Style intended for used to cover and protect catheter sites and wounds, to maintain a moist environment for wound healing with shelf life 2 years based on the documents submitted by the Indian agent/manufacturer.

### PROBLEM

M/s 3M India Limited, Plot Nos, 48-51, Electronic City, Hour Road, Bangalore - 560100 has imported the said product with a shelf life of 3 years; whereas approved shelf life is 2 years by CDSCO.

### ACTION BY

- Medical Directors/Healthcare professionals
- Distributors and the Users
- Staff involved in the management of patients.

### ACTION

This office has cancelled the registration of the product 3M Tegaderm Film Transparent Film Dressing Frame Style under the Registration Certificate no. MD-1488 dated 09.12.2014 and Import License no. MD-1488-2197 dated 21.01.2015 valid till 15.11.2017

Healthcare professionals/Distributors/Users are requested not to use or distribute 3M Tegaderm Film Transparent Film Dressing Frame Style bearing shelf life of 3 years.

## ADVERSE EFFECTS

Patients and Healthcare professionals are advised to report adverse events suspected to be associated with the use of 3M Tegaderm Film Transparent Film Dressing Frame Style to the manufacturer, Importer and CDSCO.

## CONTACTS

- Central Drugs Standard Control Organization, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, FDA Bhavan, ITO Kotla Road, New Delhi-110002  
Tel: 91-11-23236975/23236971  
Fax: 91-11-23236973  
Email: dci@nic.in
- M/s 3M Healthcare, 2510 Conway Avenue, Bldg.275-5W-06, Saint Paul, MN, USA 55144.  
Tel: +1-651-737-2027  
Fax: +1-651-737-5320  
Email: mcburville@mmm.com
- M/s 3M Company, 601, 22nd Avenue South, Brookings, South Dakota, USA 57006  
Tel: +1-605-696-1239  
Fax: +1-605-696-1337  
Email: argetting@mmm.com
- M/s. 3M India Ltd, Plot No. 48-51, Electronic City, Hosur Road, Bangalore - 560100.  
Tel: +91-80-22231414  
Fax: +91-80-22231450  
Email: ksballi@mmm.com