



ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ
ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ
Μεσογείων 284
155 62, Χολαργός
www.eof.gr

Χολαργός, 7/9 /2018
Αρ.πρωτ.: 87242

Διεύθυνση : Ελέγχου Παραγωγής και Κυκλοφορίας Προϊόντων
Τμήμα : Ελέγχου Κυκλοφορίας
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ΘΕΜΑ: «Ανάκληση παρτίδων του ιατροτεχνολογικού προϊόντος κατηγορίας IIb “Silicone Temperature Sensor Foley Catheter”»

Κατασκευαστής: Degania Silicone Ltd, Ισραήλ

Εξουσιοδοτημένος αντιπρόσωπος στην Ε.Ε.: Biometrix S.R.O, Σλοβακία

ΑΠΟΦΑΣΗ

Έχοντας υπόψη:

1. Το άρθρο 6, παρ.ΙΙ, εδ.8 του Ν. 1316/83 (ΦΕΚ 3 Α΄) «Ίδρυση, οργάνωση και αρμοδιότητες του Ε.Ο.Φ.», όπως αντικαταστάθηκε με το άρθρο 25 του Ν. 3730/2008 (ΦΕΚ 262 Β΄)
2. Το άρθρο 3, παρ. 1γ) του Ν. 1316/83 (ΦΕΚ 3 Α΄) «Ίδρυση, οργάνωση και αρμοδιότητες του Ε.Ο.Φ.»
3. Την υπ΄ αριθ. 87242/27-08-2018 ενημέρωση της εταιρείας Degania Silicone Ltd.

ΑΠΟΦΑΣΙΖΟΥΜΕ

Την ανάκληση των συνημμένων παρτίδων (βλ. Πίνακας Ι) του ιατροτεχνολογικού προϊόντος κατηγορίας IIb, “Silicone Temperature Sensor Foley Catheter”, κατόπιν παραπόνων που αναφέρθηκαν στον κατασκευαστή ότι οι αισθητήρες δίνουν χαμηλότερη ένδειξη θερμοκρασίας από την πραγματική.

Η παρούσα απόφαση εκδίδεται στο πλαίσιο της προστασίας της δημόσιας υγείας με σκοπό να ενισχύσει την εθελοντική ανάκληση της κατασκευάστριας εταιρείας Degania Silicone Ltd.

Οι εταιρείες-διανομείς του προϊόντος στην Ελλάδα, οφείλουν να επικοινωνήσουν άμεσα με τους αποδέκτες του και να αποσύρουν τις συγκεκριμένες παρτίδες από την αγορά.

Τα σχετικά παραστατικά τηρούνται για διάστημα τουλάχιστον πέντε (5) ετών και τίθενται υπόψη του ΕΟΦ, εφόσον ζητηθούν.

Η ΠΡΟΕΔΡΟΣ ΤΟΥ ΕΟΦ

ΑΙΚΑΤΕΡΙΝΗ ΑΝΤΩΝΙΟΥ

ΕΣΩΤΕΡΙΚΗ ΔΙΑΝΟΜΗ

- Δ/νση ΕΠΚΠ -Τμήμα Ελέγχου Κυκλοφορίας

ΣΥΝΗΜΜΕΝΑ

- Πίνακας Ι. Υπό ανάκληση προϊόντα

Πίνακας Ι: Υπό ανάκληση παρτίδες του ιατροτεχνολογικού προϊόντος ‘‘Silicone Temperature Sensor Foley Catheter’’

Material/Part Description:	Lot/Serial #
TSC CATHETER CLEAR 14FR STERILE	S17000191
TSC CATHETER CLEAR 14FR STERILE	S17000192
TSC CATHETER CLEAR 14FR STERILE	S17000231
TSC CATHETER CLEAR 18FR STERILE	S17000279
TSC CATHETER CLEAR 18FR STERILE	S17000280
TSC CATHETER CLEAR 14FR STERILE	S17000320
TSC CATHETER CLEAR 12FR STERILE	S17000660
TSC CATHETER CLEAR 12FR STERILE	S17000808
TSC CATHETER CLEAR 12FR STERILE	S17000809
TSC CATHETER CLEAR 18FR STERILE	S17000837
TSC CATHETER CLEAR 12FR STERILE	S17000943
TSC CATHETER CLEAR 12FR STERILE	S17000946
TSC CATHETER CLEAR 14FR STERILE	S17001226
TSC CATHETER CLEAR 12FR STERILE	S17001347
TSC CATHETER CLEAR 12FR STERILE	S17001348
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TSC CATHETER CLEAR 16FR STERILE	S17001607
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TSC CATHETER CLEAR 16FR STERILE	S17002440
TSC CATHETER CLEAR 16FR STERILE	S17002441
TSC CATHETER CLEAR 18FR STERILE	S17002452
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TSC CATHETER CLEAR 14FR STERILE	S17002784

TSC CATHETER CLEAR 8FR STERILE	S17002877
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TSC CATHETER CLEAR 16FR STERILE	S17003301
TSC CATHETER CLEAR 16FR STERILE	S17003302
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TSC CATHETER CLEAR 12FR STERILE	S17003351
TSC CATHETER CLEAR 16FR STERILE	S17003391
TSC CATHETER CLEAR 12FR STERILE	S17003439
TSC CATHETER CLEAR 16FR STERILE	S17003456
TSC CATHETER CLEAR 18FR STERILE	S17003578
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TSC CATHETER CLEAR 8FR STERILE	S17003909
TSC CATHETER CLEAR 14FR STERILE	S17003916
TSC CATHETER CLEAR 14FR STERILE	S17003917
TSC CATHETER CLEAR 12FR STERILE	S17004190
TSC CATHETER CLEAR 14FR STERILE	S17004351
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TSC CATHETER CLEAR 16FR STERILE	S17004509
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TSC CATHETER CLEAR 16FR STERILE	S17004511
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TSC CATHETER CLEAR 16FR STERILE	S17005028
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