



### DECLARATION OF CONFORMITY

**Manufacturer** : PAKTEN SAĞLIK URUNLERI SANAYI VE TICARET A.S.

**European Representative** : N/A

**Product Name** : Bed Sheet, Adult Pants, Adult Diaper

**Model** : Samll, Medium, Large and Extra Large

**Classification** : Class I (Non - Steril)

**Conformity Assesmet Route** :

- MDD (93/42/EEC) ANNEX VII
- EN 14971:2001 STANDART RISK ANALYSIS OF MEDICAL PRODUCTS
- EN 980:2003 MEDICAL DEVICE LABELING REQUIREMENTS

**General Applicable Directive** :

- EDNA REWET
- EDNA MAXIMUM SUCTION HOLD

**Standards Applied** :

- ISO 9001:2015 QUALITY MANAGEMENT SYSTEMS
- EN 14971:2001 STANDART RISK ANALYSIS OF MEDICAL PRODUCTS
- EN 980:2003 MEDICAL DEVICE LABELING REQUIREMENTS

**Place, Date Of Issue** :

PAKTEN SAĞLIK URUNLERI SANAYI VE TICARET A.S.

İbrahim Halil KURT

PAKTEN SAĞLIK ÜRÜNLERİ A.Ş.  
PAKTEN SAĞLIK ÜRÜNLERİ SANAYİ VE TİC. A.Ş.  
Başarı Organize Bölgesi 83221 No'lu Cadde / 212 Ağaoğlu My Office Kat: 4 - No: 63  
T.: +90.342.337 45 50 / F.: +90.342.337 45 55  
Ticaret Sicil No: 204600 / Mersis No: TR 33 0110 11200016  
www.pakten.com.tr / www.pakten.com.tr / 220 811 0112

Genel Müdürlük:

PAKTEN SAĞLIK ÜRÜNLERİ A.Ş.  
2. Organize Sanayi Bölgesi 83221 No'lu Cadde  
No: 9 27120 Başpınar / Gaziantep / TÜRKİYE  
T.: +90.342.337 45 50 • F.: +90.342.337 45 55

İstanbul Ofis:

212 Ağaoğlu My Office Kat: 4 - No: 63  
Mahmutbey M. Taşocağı C. 34217 İstanbul / TÜRKİYE  
T.: +90.212.777 38 23 • F.: +90.212.777 38 95

