



### 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 Bulvarı Kat: 4 No: 63 Mahmutbey M. Taşocağı C. 34217 / İSTANBUL / TÜRKİYE  
T.: +90.342.337 45 50 • F.: +90.342.337 45 55  
Ticaret Sicil No: 204600 • Mersis No: TR 90 110 1200016  
www.pakten.com.tr • 0212 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 Ağaoglu 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

