



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 SANAYİ VE TİC. A.Ş.
Büyükdere/Beşiktaş/İstanbul / TÜRKİYE
Tic. Sic. No: 204500 / Mersis No: 3401011200016
www.pakten.com.tr / İletişim No: 220 011 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

