SAĞLIK ÜRÜNLERİ A.Ş.

Pakten

DECLARATION OF CONFORMITY

Manufacturer : PAKTEN SAGLIK 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 Asssesmet 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 QUALTIY MANAGEMENT SYSTEMS
- EN 14971:2001 STANDART RISK ANALYSIS OF MEDICAL PRODUCTS
- EN 980:2003 MEDICAL DEVICE LABELING REQUIREMENTS

Place, Date Of Issue :

PAKTEN SAGLIK URUNLERI SANAYI VE TICARET A.S.

İbrahim Halil KURT

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