



EC DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices,

amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.)

Company Name : Arkan Grup Sağlık Ürünleri A.Ş.
SRN Code : TR-MF-000027138
EMDN Code : T04010103
GMDN Code : 11239
Basic UDI : 869909696HB86
Auth. Person / Title : Özcan Arkan /General Manager
Address : Velimeşe Mah. Hacı Şeremet Cad. No: 14 Ergene Tekirdağ
Phone : (+90) 282-676-46 83
Web/Mail : www.pine.com.tr

Description of Product / Product Part : Patient Diaper
Product Trademarks : Pine/Dermaped
Product Type : Various Sizes

PRODUCTION SITE : Arkan Grup Sağlık Ürünleri A.Ş.
Velimeşe Mah. Hacı Şeremet Cad. No: 14 Ergene Tekirdağ
(+90) 282-676-46 83
www.pine.com.tr

Compliance Directives:
2017/745 Regulations of the European Parliament & Council

Harmonized Standards:
EN ISO 13485: 2016 / EN ISO 14971: 2019 / ISO TR 24971: 2020 / EN 15223-1: 2021 / EN ISO 20417:2021 / EN ISO 10993-1:2020 / EN ISO 10993-5:2009 / EN ISO 10993-10:2023
Manufactured according to harmonized standards.

Product Class Information:
2017/745 Regulations of the European Parliament & Council (Annex VIII, Rule 1)
We declare that it complies with the provisions of Class I Other (No measurement function, non-sterile, non-reusable).

This Declaration of conformity is issued only, under responsibility of **Arkan Grup Sağlık Ürünleri A.Ş.** Medical device (s) listed in Annex-1, related to Medical devices (EU) MDR 2017/745

We declare that it meets the provision of the regulation. This statement is being supported by quality system approval ISO 13485, given by **Institute of Global Certification** all supporting documents stored at Manufacturer's premises.

This declaration is edited according to (EU) No. 2017/745 EUROPEAN PARLIAMENT and COUNCIL STATEMENT Annex IV. EU Declaration of conformity.

Our Pine and Dermaped branded products, whose product names, codes, models and Basic-UDI codes are given below;

REF CODE	PRODUCT NAME	BRAND	PRODUCT TYPE	PACKAGING	BARCODE NO
PNSM-P30	Adult Diaper	Pine	Small	30 PCS	8699096966059
PNMD-P30	Adult Diaper	Pine	Medium	30 PCS	8699096966066
PNLG-P30	Adult Diaper	Pine	Large	30 PCS	8699096966073
PNXL-P30	Adult Diaper	Pine	XLarge	30 PCS	8699096966080
ADMD-P09	Adult Diaper	Pine	Medium	9 PCS	86990969660613
ADLG-P07	Adult Diaper	Pine	Large	7 PCS	86990969660620
AP-M10	Adult Diaper Pants	Pine	Medium	10 PCS	86990969660811
AP-L8	Adult Diaper Pants	Pine	Large	8 PCS	86990969660828
AP-XL7	Adult Diaper Pants	Pine	XLarge	7 PCS	86990969660835
AP-M30	Adult Diaper Pants	Pine	Medium	30 PCS	86990969660880
AP-L30	Adult Diaper Pants	Pine	Large	30 PCS	86990969660897
AP-XL30	Adult Diaper Pants	Pine	XLarge	30 PCS	86990969660903
DPSM-P30	Adult Diaper	Dermaped	Small	30 PCS	8699096966011
DPMD-P30	Adult Diaper	Dermaped	Medium	30 PCS	8699096966028
DPLG-P30	Adult Diaper	Dermaped	Large	30 PCS	8699096966035
DPXL-P30	Adult Diaper	Dermaped	XLarge	30 PCS	8699096966042
DPSM-P19	Adult Diaper	Dermaped	Small	19 PCS	8699096966127
DPMD-P17	Adult Diaper	Dermaped	Medium	17 PCS	8699096966134
DPLG-P15	Adult Diaper	Dermaped	Large	15 PCS	8699096966141
DPXL-P13	Adult Diaper	Dermaped	XLarge	13 PCS	8699096966158

Table 1. Product List

GMDN Code Explanation: 11239

Adult nappy

A disposable undergarment (a nappy or diaper) composed of absorbent material and worn between the legs used to collect urine and faeces from an incontinent adult patient. This is a single-use device.

First CE Marking Date : 20.01.2022
Declaration Date : 17.02.2025
Declaration Place : İstanbul, Türkiye
Declared by : Özcan ARKAN
Signature : 