CE

EC DECLARATION OF CONFORMITY

(EU) No. 2017/745 Regulations of the European Parliament & Council

Company Name	: Arkan Grup Sağlık Ürünleri A.Ş.
SRN Code	: TR-MF-000027138
EMDN Code	: T04010103
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 1 : 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
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.

Digitally signed by Granaci Boris
Date: 2025.06.19 11:57:04 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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	BASIC UDI	GMDN CODE	PRODUCTION SITE
ADSM-P30	Adult Diaper	Pine	Small	30 PCS	8699096960804	869909696HB86	11239	1
ADMD-P30	Adult Diaper	Pine	Medium	30 PCS	8699096960637	869909696HB86	11239	1
ADLG-P30	Adult Diaper	Pine	Large	30 PCS	8699096960644	869909696HB86	11239	1
ADXL-P30	Adult Diaper	Pine	XLarge	30 PCS	8699096961078	869909696HB86	11239	1
PNSM-P30	Adult Diaper	Pine	Small	30 PCS	8699096966059	869909696HB86	11239	1
PNMD-P30	Adult Diaper	Pine	Medium	30 PCS	8699096966066	869909696HB86	11239	1
PNLG-P30	Adult Diaper	Pine	Large	30 PCS	8699096966073	869909696HB86	11239	1
PNXL-P30	Adult Diaper	Pine	XLarge	30 PCS	8699096966080	869909696HB86	11239	1
ADMD-P09	Adult Diaper	Pine	Medium	9 PCS	8699096960613	869909696HB86	11239	1
ADLG-P07	Adult Diaper	Pine	Large	7 PCS	8699096960620	869909696HB86	11239	1
AP-M10	Adult Diaper Pants	Pine	Medium	10 PCS	8699096960811	869909696HB86	11239	1,2,3,4
AP-L8	Adult Diaper Pants	Pine	Large	8 PCS	8699096960828	869909696HB86	11239	1,2,3,4
AP-XL7	Adult Diaper Pants	Pine	XLarge	7 PCS	8699096960835	869909696HB86	11239	1,2,3,4
AP-M30	Adult Diaper Pants	Pine	Medium	30 PCS	8699096960880	869909696HB86	11239	1,2,3,4
AP-L30	Adult Diaper Pants	Pine	Large	30 PCS	8699096960897	869909696HB86	11239	1,2,3,4
AP-XL30	Adult Diaper Pants	Pine	XLarge	30 PCS	8699096960903	869909696HB86	11239	1,2,3,4
DPSM-P30	Adult Diaper	Dermaped	Small	30 PCS	8699096966011	869909696HB86	11239	1
REF CODE	**PRODUCT NAME**	**BRAND**	**PRODUCT TYPE**	**PACKAGING**	**BARCODE NO**	**BASIC UDI**	**GMDN CODE**	**PRODUCTION SITE**
DPMD-P30	Adult Diaper	Dermaped	Medium	30 PCS	8699096966028	869909696HB86	11239	1
DPLG-P30	Adult Diaper	Dermaped	Large	30 PCS	8699096966035	869909696HB86	11239	1
DPXL-P30	Adult Diaper	Dermaped	XLarge	30 PCS	8699096966042	869909696HB86	11239	1
DPSM-P19	Adult Diaper	Dermaped	Small	19 PCS	8699096966127	869909696HB86	11239	1
DPMD-P17	Adult Diaper	Dermaped	Medium	17 PCS	8699096966134	869909696HB86	11239	1
DPLG-P15	Adult Diaper	Dermaped	Large	15 PCS	8699096966141	869909696HB86	11239	1

DPXL-P13	Adult Diaper	Dermaped	XLarge	13 PCS	8699096966158	869909696HB86	11239	1

Table 1. Product List

First CE Marking Date : 20.01.2022
Declaration Date : 17.05.2023
Declaration Place : İstanbul, Türkiye
Declared by : Özcan ARKAN
Signature :