



## 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](http://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.

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
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**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** : 