



## 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. )

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

|  |                  |
|--|------------------|
| <b>Description of Product / Product Part</b> | : Patient Diaper |
| <b>Product Trademarks</b>                    | : Pine/Dermaped  |
| <b>Product Type</b>                          | : Various Sizes  |

|                        |  |
|------------------------|--|
| <b>PRODUCTION SITE</b> | : Arkan Grup Sağlık Ürünleri A.Ş.<br>Velimeşe Mah. Hacı Şeremet Cad. No: 14 Ergene Tekirdağ<br>(+90) 282-676-46 83<br><a href="http://www.pine.com.tr">www.pine.com.tr</a> |
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#### 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     | 8699096960613 |
| ADLG-P07 | Adult Diaper       | Pine     | Large        | 7 PCS     | 8699096960620 |
| AP-M10   | Adult Diaper Pants | Pine     | Medium       | 10 PCS    | 8699096960811 |
| AP-L8    | Adult Diaper Pants | Pine     | Large        | 8 PCS     | 8699096960828 |
| AP-XL7   | Adult Diaper Pants | Pine     | XLarge       | 7 PCS     | 8699096960835 |
| AP-M30   | Adult Diaper Pants | Pine     | Medium       | 30 PCS    | 8699096960880 |
| AP-L30   | Adult Diaper Pants | Pine     | Large        | 30 PCS    | 8699096960897 |
| AP-XL30  | Adult Diaper Pants | Pine     | XLarge       | 30 PCS    | 8699096960903 |
| 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** : 