

EU DECLARATION OF CONFORMITY

Manufacturer: **GENTUĞ TEKSTİL ÜRÜNLERİ SAN. VE TİC. A.Ş**
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SRN Number:

The company Gentuğ Tekstil Ürünleri San. ve Tic. A.Ş here with declares that all mentioned products in this declaration meets all applicable provisions of the EU 2017/745 Medical Device Regulation (with amendment 2020/561, 2023/502, 2023/607). Gentuğ Tekstil Ürünleri San. ve Tic. A.Ş takes the sole responsibility of the products, under the prescribed and reasonably foreseeable conditions of storage and use. All proofs and documents are kept under the responsibility of the manufacturer.

Ref Product Code	Products	Basic UDI-DI
361.0010083.07500850.000	CARETEX ABSO 5 LAYER REUSABLE UNDERPAD (STANDARD) 75X85	8682550ABSO7C
361.0020083.07500850.000	CARETEX ABSO 5 LAYER REUSABLE UNDERPAD (WINGED) 75X85	
361.0010083.07500900.000	CARETEX ABSO 5 LAYER REUSABLE UNDERPAD (STANDARD) 75X90	
361.0020083.07500900.000	CARETEX ABSO 5 LAYER REUSABLE UNDERPAD (WINGED) 75X90	
361.0010083.08500900.000	CARETEX ABSO 5 LAYER REUSABLE UNDERPAD (STANDARD) 85X90	
361.0020083.08500900.000	CARETEX ABSO 5 LAYER REUSABLE UNDERPAD (WINGED) 85X90	
361.0010089.07500850.000	CARETEX ABSO 4 LAYER REUSABLE UNDERPAD (STANDARD) 75X85	
361.0020089.07500850.000	CARETEX ABSO 4 LAYER REUSABLE UNDERPAD (WINGED) 75X85	
361.0010089.07500900.000	CARETEX ABSO 4 LAYER REUSABLE UNDERPAD (STANDARD) 75X90	
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361.0020089.08500900.000	CARETEX ABSO 4 LAYER REUSABLE UNDERPAD (WINGED) 85X90	

EMDN Code	EMDN Description
T040102	ABSORBENT UNDERPADS

Conformity Assessment Route:

EU 2017/745 Medical Device Regulation Annex IV EU Declaration of Conformity

Product Risk Rule, Class:

Annex-8 Rule I, Class I

In order to ensure product safety and performance, throughout the design, production, storage and distribution processes, the mandatory latest version of the following standards given below were applied.

Applicable Harmonised Standards;

EN ISO 13485:2016 +A11:2021, EN ISO 14971:2019, EN ISO 15223-1:2021, EN 7010:2020, EN ISO 20417:2021

Reference and Standards for product safety and performance;

ISO 3758:2012

Applicable Other Regulations;

On behalf of the Manufacturer
KEMAL KARABACAK
Responsible Manager
GEREDE, BOLU, TÜRKİYE
31.10.2023

G E N T U Ğ
TEKSTİL ÜRÜNLERİ SAN. VE TİC. A.Ş.
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