

EU SELF 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 meet 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.

NO	MATERIAL DESCRIPTION	Basic UDI -DI
S38268	ABSO BUDGET CHAIR PAD 4 LAYER - BLUE MAB1.5.1.S.TMV.HS.050X060	8682550ABSO7C
S38279	ABSO BUDGET CHAIR PAD 4 LAYER - GREEN MAB1.5.1.S.TYL.HS.050X060	
S38281	ABSO BUDGET CHAIR PAD 4 LAYER - BROWN MAB1.5.1.S.TKH.HS.050X060	
S38293	ABSO BUDGET CHAIR PAD 4 LAYER - BURGUNDY MAB1.5.1.S.TBR.HS.050X060	
S38309	ABSO BUDGET CHAIR PAD 4 LAYER 500X600MM MAB1.4.1.CS.BS.050X060	
S38311	ABSO BUDGET CHAIR PAD 4 LAYER 500X600MM MAB1.5.1.CL.BS.050X060	
S38323	ABSO PREMIUM CHAIR PAD 5 LAYER - GREEN MAB1.5.1.S.THK.HS.050X050	
S38335	ABSO PREMIUM CHAIR PAD 5 LAYER - PINK MAB1.5.1.S.TPB.HS.050X050	
S38347	ABSO PREMIUM CHAIR PAD 5 LAYER - BLUE MAB1.5.1.S.TMV.HS.050X050	
S38359	ABSO PREMIUM CHAIR PAD 5 LAYER - BURGUNDY MAB1.5.1.S.TBR.HS.050X050	
S38384	ABSO ECO BEDPAD 4 LAY-1150X850MM NO WING MAKD.4.1.BY.TY.RM.085X115	
S38396	ABSO ECO BEDPAD 4 LAY-1150X850MM W/WINGS MAKD.4.1.KN.TY.RM.085X115	
S38402	ABSO PREM BEDPAD 5 LAY-910X910MM-NO WING MASD.5.1.BY.TY.RM.091X091	
S38414	ABSO PREM BEDPAD 5 LAY-910X910MM-W/WING MASD.5.1.KB.TY.RM.091X091	
S38426	ABSO PREM BEDPAD 5 LAY-1150X850MM-NO WING MASD.5.1.BY.TY.RM.085X115	
S38438	ABSO PREM BEDPAD 5 LAY-1150X850MM-W/WING MASD.5.1.KB.TY.RM.085X115	

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
24.09.2024

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ONUR HÜRGEL
Member Of the Board
GUNGOREN, ISTANBUL, TÜRKİYE
24.09.2024

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