WingMED®
Orthopedic Equipments

DECLARATION OF CONFORMITY EC

DOGAM MEDIKAL COMPANY MANUFACTURER OF OTHOPEDIC EQUIPMENTS

UNDER WINGMED BRAND DECLARES THAT

PRODUCT GROUP: SHOULDER & ELBOW GROUP

LIST OF ITEMS IN APPENDIX NO.1

Marked with the CE sign is Class I medical device, of rule 1, consistent with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
Conformity assessment was carried out in accordance with the requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council.
In order to demonstrate the safety and effectiveness of the medical device, the following standards were used to assess conformity:

ISO 13485:2016
This certificate is valid concerning all activities related to; Medical Products Quality Management Systems, Requirements For Law Regulations Aims.

ISO 9001:2015
This certificate is valid concerning all activities related to; Operational Efficiency, Risk Management, Customer Satisfaction, Requirements for International Standarts.

Harmonizing Standarts:
•EN ISO 980: 1996/A1: 1999 Graphical Symbols Used In Labeling Medical Devices
•EN ISO 1041: 1998 Interest With The Medical Devices Provided By The Manufacturer
•EN ISO 14971-1: 1998 Exposure Management
•EN ISO 15223-1: 2017-02: Medical Devices Labelling and Information

THIS DECLARATION HAS BEEN ISSUED ON THE RESPONSIBILITY OF THE MANUFACTURER(BASIC UDI-DI 86811903200TW)

Dogam Medikal Kozmetik Gıda Tekstil Ithalat Ihracat Sanayi ve Tic. LTD. STI.
www.wingmed.com.tr - info@wingmed.com.tr
Seyhan Mahallesi 629/12 Sokak No: 2-4 Buca Izmir-Turkey

DOĞAM MEDİKAL KOZMETİK GIDA TEKS.İTH.İHR.SAN.VE TİC.LTD.ŞTİ.
Seyhan Mahç 629/12 Sk. No:2-4 Kat:3 Buca/İZMİR
Gaziemir V.D:3020522702 Tic. Sic.No:178596
Tel: 0 232 469 1 444

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APPENDIX NO.1

PRODUCT GROUP: SHOULDER & ELBOW GROUP

PRODUCT NAME	PRODUCT CODE	GMDN CODE	PRODUCT UDI-DI CODE
EPICONDYLITIS BANDAGE (UNIVERSAL)	W 201	41053	8681190362226
EPICONDYLITIS BANDAGE WITH SILICONE PAD (UNIVERSAL)	W 202	41053	8681190362233
TENNIS ELBOW SUPPORT (UNIVERSAL)	W 203	41053	8681190362240
BASIC ELBOW SUPPORT (UNIVERSAL)	W 205	41053	8681190362301
SPORTIVE ELBOW SUPPORT WITH PAD (SMALL)	W 206-S	41053	8682692600632
SPORTIVE ELBOW SUPPORT WITH PAD (MEDIUM)	W 206-M	41053	8682692600649
SPORTIVE ELBOW SUPPORT WITH PAD (LARGE)	W 206-L	41053	8682692600656
SPORTIVE ELBOW SUPPORT WITH PAD (X LARGE)	W 206-XL	41053	8682692600663
SPORTIVE ELBOW SUPPORT WITH PAD (XX LARGE)	W 206-XXL	41053	8682692600670
ELBOW IMMOBILIZER (20 CM)	W 207-20	41053	8681190362325
ELBOW IMMOBILIZER (25 CM)	W 207-25	41053	8681190360918
ELBOW IMMOBILIZER (30 CM)	W 207-30	41053	8681190360925
CUBITAL TUNNEL ELBOW (STD1=S-M)	W 223-STD1	41053	8681190368747
CUBITAL TUNNEL ELBOW (STD2=L-XL-XXL)	W 223-STD2	41053	8681190361632
THERMAL ARM BANDAGE (UNIVERSAL)	W 228	41053	8682692600120
PRACTICAL ARM SLING (UNIVERSAL)	W 208	13622	8681190362332
ARM SLING (PERFORATED) (SMALL)	W 209-S	13622	8681190362349
ARM SLING (PERFORATED) (MEDIUM)	W 209-M	13622	8681190362356
ARM SLING (PERFORATED) (LARGE)	W 209-L	13622	8681190362363
ARM SLING (PERFORATED) (X LARGE)	W 209-XL	13622	8681190362370
ARM SLING (PERFORATED) (XX LARGE)	W 209-XXL	13622	8681190362387
ARM SLING WITH ADDITIONAL BELT (PERFORATED) (SMALL)	W 210-S	13622	8681190362394
ARM SLING WITH ADDITIONAL BELT (PERFORATED) (MEDIUM)	W 210-M	13622	8681190362400
ARM SLING WITH ADDITIONAL BELT (PERFORATED) (LARGE)	W 210-L	13622	8681190362417
ARM SLING WITH ADDITIONAL BELT (PERFORATED) (X LARGE)	W 210-XL	13622	8681190362424
ARM SLING WITH ADDITIONAL BELT (PERFORATED) (XX LARGE)	W 210-XXL	13622	8681190362431
ARM SLING WITH ADDITIONAL BELT (LUX) (SMALL)	W 211-S	13622	8681190362448
ARM SLING WITH ADDITIONAL BELT (LUX) (MEDIUM)	W 211-M	13622	8681190362455
ARM SLING WITH ADDITIONAL BELT (LUX) (LARGE)	W 211-L	13622	8681190362462
ARM SLING WITH ADDITIONAL BELT (LUX) (X LARGE)	W 211-XL	13622	8681190362479
ARM SLING WITH ADDITIONAL BELT (LUX) (XX LARGE)	W 211-XXL	13622	8681190362486
ARM SLING 30 DEGREES (UNIVERSAL)	W 212	13622	8681190362493
ARM SLING 45-60 DEGREES (UNIVERSAL)	W 213	13622	8681190362509
ARM ABDUCTION ORTHOSIS PLUS (UNIVERSAL)	W 226	13622	8682692600137
SHOULDER SUPPORT (UNIVERSAL)	W 214	13622	8681190362516
ICE BAG SHOULDER SUPPORT (UNIVERSAL)	W 227	41465	8682692600144
ACROMIO-CLAVICULAR BANDAGE (STIMSON BANDAGE) (RIGHT)(SMALL)	W 225-SAĞ-S	13622	8682692600182
ACROMIO-CLAVICULAR BANDAGE (STIMSON BANDAGE) (RIGHT)(MEDIUM)	W 225-SAĞ-M	13622	8682692600199
ACROMIO-CLAVICULAR BANDAGE (STIMSON BANDAGE) (RIGHT)(LARGE)	W 225-SAĞ-L	13622	8682692600205
ACROMIO-CLAVICULAR BANDAGE (STIMSON BANDAGE) (LEFT)(SMALL)	W 225-SOL-S	13622	8682692600151
ACROMIO-CLAVICULAR BANDAGE (STIMSON BANDAGE) (LEFT)(MEDIUM)	W 225-SOL-M	13622	8682692600168
ACROMIO-CLAVICULAR BANDAGE (STIMSON BANDAGE) (LEFT)(LARGE)	W 225-SOL-L	13622	8682692600175
CLAVICLE BANDAGE (STD1=S-M)	W 215-STD1	13622	8681190362523
CLAVICLE BANDAGE (STD2=L-XL-XXL)	W 215-STD2	13622	8681190360932
CLAVICLE BANDAGE WITH PVC SUPPORT (STD1=S-M)	W 216-STD1	13622	8681190362530
CLAVICLE BANDAGE WITH PVC SUPPORT (STD2=L-XL-XXL)	W 216-STD2	13622	8681190360949
VELPEAU BANDAGE (STD1=S-M)	W 217-STD1	13622	8681190362547
VELPEAU BANDAGE (STD2=L-XL-XXL)	W 217-STD2	13622	8681190360956
ADJUSTABLE ELBOW CONTRACTURE SPLINT WITH HAND SUPPORT (RIGHT) (STD1=S-M)	W 218-SAĞ-STD1	41053	8681190360963
ADJUSTABLE ELBOW CONTRACTURE SPLINT WITH HAND SUPPORT (STD2=L-XL-XXL)	W 218-SAĞ-STD2	41053	8681190360970
ADJUSTABLE ELBOW CONTRACTURE SPLINT WITH HAND SUPPORT (LEFT) (STD1=S-M)	W 218-SOL-STD1	41053	8681190362554
ADJUSTABLE ELBOW CONTRACTURE SPLINT WITH HAND SUPPORT (LEFT) (STD2=L-XL-XXL)	W 218-SOL-STD2	41053	8681190362561
ADJUSTABLE ELBOW CONTRACTURE SPLINT (RIGHT) (STD1=S-M)	W 219-SAĞ-STD1	41053	8681190360987
ADJUSTABLE ELBOW CONTRACTURE SPLINT (RIGHT) (STD2=L-XL-XXL)	W 219-SAĞ-STD2	41053	8681190360994
ADJUSTABLE ELBOW CONTRACTURE SPLINT (LEFT) (STD1=S-M)	W 219-SOL-STD1	41053	8681190362578
ADJUSTABLE ELBOW CONTRACTURE SPLINT (LEFT) (STD2=L-XL-XXL)	W 219-SOL-STD2	41053	8681190362585

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Gaziemir V.D:3020522702 Tic. Sic.No:178596
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ÜRÜN AÇIKLAMASI	ÜRÜN KODU	GMDN KODU	ÜRÜN UDI-DI KODU
HUMERUS BRACE (RIGHT)(SMALL)	W 220-SAĞ-S	41455	8681190361007
HUMERUS BRACE (RIGHT)(MEDIUM)	W 220-SAĞ-M	41455	8681190361014
HUMERUS BRACE (RIGHT)(LARGE)	W 220-SAĞ-L	41455	8681190361021
HUMERUS BRACE (LEFT)(SMALL)	W 220-SOL-S	41455	8681190362592
HUMERUS BRACE (LEFT)(MEDIUM)	W 220-SOL-M	41455	8681190362608
HUMERUS BRACE (LEFT)(MEDIUM)	W 220-SOL-L	41455	8681190362615
HUMERUS BRACE PLUS (UNIVERSAL)	W 222	41455	8681190368754
SPORTIVE WOVEN ELASTIC ELBOW SUPPORT (SMALL)	W 224-S	41053	8682692600793
SPORTIVE WOVEN ELASTIC ELBOW SUPPORT (MEDIUM)	W 224-M	41053	8682692600809
SPORTIVE WOVEN ELASTIC ELBOW SUPPORT (LARGE)	W 224-L	41053	8682692600816
SPORTIVE WOVEN ELASTIC ELBOW SUPPORT (X LARGE)	W 224-XL	41053	8682692600823
WOVEN ELBOW SUPPORT (SMALL)	W 221-S	41053	8681190368693
WOVEN ELBOW SUPPORT (MEDIUM)	W 221-M	41053	8681190368709
WOVEN ELBOW SUPPORT (LARGE)	W 221-L	41053	8681190368716
WOVEN ELBOW SUPPORT (X LARGE)	W 221-XL	41053	8681190368723
WOVEN ELBOW SUPPORT (XX LARGE)	W 221-XXL	41053	8681190368730
WOVEN EPICONDYLITIS ELBOW SUPPORT (SMALL)	W 204-S	41053	8681190362257
WOVEN EPICONDYLITIS ELBOW SUPPORT (MEDIUM)	W 204-M	41053	8681190362264
WOVEN EPICONDYLITIS ELBOW SUPPORT (LARGE)	W 204-L	41053	8681190362271
WOVEN EPICONDYLITIS ELBOW SUPPORT (X LARGE)	W 204-XL	41053	8681190362288
WOVEN EPICONDYLITIS ELBOW SUPPORT (XX LARGE)	W 204-XXL	41053	8681190362295
ARM SLING 30 DEGREES (UNIVERSAL)	W 229	13622	8682692602742
BASIC ELBOW SUPPORT (SMALL)	W 230-S	41053	8682692602759
BASIC ELBOW SUPPORT (MEDIUM)	W 230-M	41053	8682692602766
BASIC ELBOW SUPPORT (LARGE)	W 230-L	41053	8682692602773
BASIC ELBOW SUPPORT (X LARGE)	W 230-XL	41053	8682692602780
BASIC ELBOW SUPPORT (XX LARGE)	W 230-XXL	41053	8682692602797
TENNIS ELBOW SUPPORT (SMALL)	W 231-S	41053	8682692602803
TENNIS ELBOW SUPPORT (MEDIUM)	W 231-M	41053	8682692602810
TENNIS ELBOW SUPPORT (LARGE)	W 231-L	41053	8682692602827
TENNIS ELBOW SUPPORT (X LARGE)	W 231-XL	41053	8682692602834
TENNIS ELBOW SUPPORT (XX LARGE)	W 231-XXL	41053	8682692602841
ICE BAG SHOULDER SUPPORT (UNIVERSAL)	W 232	41053	8682692602858
DOUBLE ICE BAG SHOULDER SUPPORT (UNIVERSAL)	W 233	41465	8682692602865
EPICONDYLITIS BANDAGE WITH EASY SYSTEM (SMALL)	W 234-S	41053	8682692602872
EPICONDYLITIS BANDAGE WITH EASY SYSTEM (MEDIUM)	W 234-M	41053	8682692602889

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