



ATILIM SAĞLIK A.Ş.

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

We here with declare, Manufacturer / EU Representative:

ATILIM SAĞLIK A.Ş

Yakuplu Mah. Hürriyet Bulvarı 59.Sok No:32/A Kat:3 Beylikdüzü | İstanbul | Turkey

that the following described product in our delivered version complies with the appropriate basic safety and health requirements of the Medical Device Regulation(EU)2017/745 based on its design and type, as brought into circulation by us. In case of alteration of the product, not agreed upon by us, this declaration will lose its validity.

The declaration of conformity is valid in connection with the release technical document MDR-ATI-WF001. All the supporting documentation is retained at the premises of the manufacturer.

Description Of The Product/Products Part	:	ORTHOPEDIC PRODUCTS
Product Type	:	DIFFERENT SIZE
Product Commercial Brand	:	PUFFIX
Application EC Directives	:	Medical Device Regulation(EU)2017/745
Applicable Harmonized Standards	:	EN ISO 9001:2015 EN ISO 13485:2016 ISO14001: 2015
Applicable National Technical Standards and Specifications	:	TS EN 46003, TS 7199
Classification	:	CLASS 1

ATTACHED LISTS

CODE GMDM	REF	DESIGNATION	SIZES
41039	PF - 100	SOFT COLLAR	XS-S-M-L-XL-XXL
41039	PF - 101	SUPPORT SOFT COLLAR	XS-S-M-L-XL-XXL
41039	PF - 102	NELSON COLLAR	XS-S-M-L-XL-XXL
41039	PF - 103	NELSON COLLAR WITH CHIN SUPPORT	XS-S-M-L-XL-XXL
41245	PF - 104	NELSON COLLAR	XS-S-M-L-XL-XXL
41245	PF - 105	NELSON COLLAR WITH CHIN SUPPORT	XS-S-M-L-XL-XXL
41245	PF - 106	PHILADELPHIA COLLAR	XS-S-M-L-XL-XXL
41245	PF - 107	PHILADELPHIA COLLAR TRACHEOSTOMY COLLAR	XS-S-M-L-XL-XXL
41245	PF - 108	CERVICAL COLLAR	XS-S-M-L-XL-XXL
13622	PF - 200	CERVICAL COLLAR WITH CHIN	XS-S-M-L-XL-XXL
13622	PF - 201	MINERVA CERVICAL ORTHOSIS	XS-S-M-L-XL-XXL
41141	PF - 202	ARM SLING (SPONGE)	STANDARD
41141	PF - 203	ARM SLING (FLEXI)	STANDARD
41141	PF - 204	ACTIVE ARM SLING (30 DEGREE)	XS-S-M-L-XL-XXL
41141	PF - 205	ACTIVE ARM SLING (45-60 DEGREE)	STANDARD
41465	PF - 206	SHOULDER SUPPORT	XS-S-M-L-XL-XXL
41465	PF - 300	SHOULDER SUPPORT BANDAGE (VELPAU)	XS-S-M-L-XL-XXL
41465	PF - 301	CLAVICLE BANDAGE	STANDARD
41465	PF - 302	ELASTIC ELBOW SUPPORT	XS-S-M-L-XL-XXL
41465	PF - 303	NEOPREN EPICONDYLITIS BANDAGE	STANDARD

41053	PF - 304	TENNIS ELBOW SUPPORT WITH EPICONDYLITIS	XS-S-M-L-XL-XXL-STANDARD
41053	PF - 305	KNITTED ELBOW SUPPORT WITH EPICONDYLITIS	XS-S-M-L-XL-XXL-STANDARD
41053	PF - 306	KNITTED ELBOW SUPPORT	STANDARD
41053	PF - 400	ELBOW ROM ORTHOSIS	XS-S-M-L-XL-XXL-STANDARD
41053	PF - 401	ELBOW ROM ORTHOSIS	XS-S-M-L-XL-XXL-STANDARD
41053	PF - 402	NEOPREN WRIST SPLINT WITH THUMB SUPPORT	STANDARD
41053	PF - 403	NEOPREN WRIST SPLINT	XS-S-M-L-XL-XXL-STANDARD
41459	PF - 404	WRIST SPLINT AIRTEX	STANDARD
41459	PF - 405	WRIST SPLINT WITH STHUMB SUPPORT AIRTEX	RIGHT-LEFT STANDARD
41459	PF - 406	WRIST SPLINT WITH STHUMB SUPPORT	RIGHT-LEFT STANDARD
41459	PF - 407	WRIST SPLINT	RIGHT-LEFT /S-M-L-XL-XXL/
41459	PF - 408	WRIST SPLINT	RIGHT-LEFT STANDARD
41459	PF - 409	KNITTED WRIST SPLINT	RIGHT-LEFT /S-M-L-XL-XXL/
41459	PF - 410	THERMOPLASTIC DYNAMIC HAND FINGER SPLINT	RIGHT-LEFT /S-M-L-XL-XXL/
41459	PF - 411	THERMOPLASTIC KLEINERT HAND FINGER SPLINT	RIGHT-LEFT STANDARD
41459	PF - 500	THERMOPLASTIC ANTI SPASTICITY HAND FINGER SPLINT	RIGHT-LEFT STANDARD
41459	PF - 501	THERMOPLASTIC RESTING HAND FINGER SPLINT	RIGHT-LEFT STANDARD
41459	PF - 502	FLAT FINGER SPLINT	RIGHT-LEFT /S-M-L-XL-XXL/
41459	PF - 503	MALLET FINGER SPLINT	RIGHT-LEFT /S-M-L-XL-XXL/
41459	PF - 504	BASEBALL FINGER SPLINT	RIGHT-LEFT /S-M-L-XL-XXL/
41459	PF - 600	STABILIZATION FINGER SPLINT	RIGHT-LEFT /S-M-L-XL-XXL/

41459	PF - 601	FROG FINGER SPLINT	RIGHT-LEFT /S-M-L-XL-XXL/
41456	PF - 602	CHEST CORSET WITH STEEL SUPPORT	S-M-L-XL-XXL
41456	PF - 603	DORSOLUMBAR CORSET	S-M-L-XL-XXL
41456	PF - 604	ABDOMINAL CORSET	S-M-L-XL-XXL
41456	PF - 605	LUMBOSTAD CORSET (26CM)	S-M-L-XL-XXL
41456	PF - 606	BELLY FINGER CORSET	S-M-L-XL-XXL
41456	PF - 607	LUMBOSACRAL CORSET (32CM)	S-M-L-XL-XXL
41454	PF - 608	POSTUREX CORSET	XS-S-M-L-XL-XXL
41454	PF - 609	KNITTED LUMBOSACRAL CORSET	STANDARD
41454	PF - 610	KNITTED LUMBOSACRAL CORSET WITH PAD	XS-S-M-L-XL-XXL-XXXL
41454	PF - 611	WOOLEN CORSET CAMEL	XS-S-M-L-XL-XXL-XXXL
41454	PF - 700	PREGNANCY CORSET	STANDARD
41454	PF - 701	COLOSTOMY CORSET	XS-S-M-L-XL-XXL-XXXL
41454	PF - 702	L.S.O CORSET	STANDARD
41454	PF - 703	T.L.S.O CORSET	XS-S-M-L-XL-XXL-XXXL
41454	PF - 704	HYPEREXSTANCE CORSET	XS-S-M-L-XL-XXL
41454	PF - 001	HYPEREXSTANCE CORSET	XS-S-M-L-XL-XXL
41454	PF - 002	PECTUS ORTHOSIS	XS-S-M-L-XL-XXL-STANDARD-GRAND-PETIT
35409	PF - 800	INGUINAL TRUSS (SINGLE SIDED)	XS-S-M-L-XL-XXL-STANDARD
35409	PF - 801	INGUINAL TRUSS (DOUBLE SIDED)	STANDARD
35409	PF - 802	SIMPLE KNEE SUPPORT	DROIT - LEFT
41065	PF - 803	PATELLA KNEE SUPPORT	S-M-L-XL-XXL-XXXL
41065	PF - 804	PATELLA AND LIGAMENT KNEE SUPPORT	S-M-L-XL-XXL-XXXL

41065	PF - 805	HINGED KNEE SUPPORT	S-M-L-XL-XXL-XXXXL
41065	PF - 806	KNEE SUPPORT FOR ANT.	S-M-L-XL-XXL-XXXXL
41065	PF - 807	KNEE SUPPORT FOR ANT. CRUCIATE LIGAMENT	S-M-L-XL-XXL-XXXXL
41065	PF - 808	PATELLA TENDON BAND	STANDARD
41065	PF - 809	WOOLEN KNEE SUPPORT CAMEL	S-M-L-XL-XXL-XXXXL
41065	PF - 810	KNITTED SIMPLE KNEE SUPPORT	STANDARD
41065	PF - 811	KNEE PATELLA KNEE SUPPORT	S-M-L-XL-XXL-XXXXL
41065	PF - 812	KNEE PATELLA AND LIGAMENT KNEE SUPPORT	S-M-L-XL-XXL-XXXXL
41065	PF - 813	KNITTED HINGED KNEE SUPPORT	STANDARD
41065	PF - 814	IMMOBILIZER	S-M-L-XL-XXL-XXXXL
41065	PF - 003	ANGLE ADJUSTED BRACE	S-M-L-XL-XXL-XXXXL
41065	PF - 555	ANGLE ADJUSTED BRACE (PUFFIX PLUS)	S-M-L-XL-XXL-XXXXL
41065	PF - 556	HIP BRACE	S-M-L-XL-XXL-XXXXL
41065	PF - 557	SIMPLE ANKLE SUPPORT	S-M-L-XL-XXL-XXXXL
41065	PF - 558	MALLEOL ANKLE SUPPORT	S-M-L-XL-XXL-XXXXL
41065	PF - 559	LIGAMENT ANKLE SUPPORT	STANDARD
41065	PF - 560	KNITTED SIMPLE ANKLE SUPPORT	STANDARD
41065	PF - 561	KNITTED MALLEOL ANKLE SUPPORT	S-M-L-XL-XXL
36206	PF - 562	KNITTED ACHILLES TENDON ANKLE SUPPORT	S-M-L-XL-XXL
36206	PF - 563	ANKLE SUPPORT WITH PAD	S-M-L-XL-XXL
36206	PF - 564	ANKLE SUPPORT WITH AIR	S-M-L-XL-XXL
36206	PF - 565	DORSI - FLEXION BANDAGE	S-M-L-XL-XXL
36206	PF - 566	REFLEKS AFO	S-M-L-XL-XXL

36206	PF - 567	FOOT GUARD	STANDARD
36206	PF - 568	FOOT GUARD ADJUSTABLE	STANDARD
36206	PF - 900	R.O.M. WALKER	STANDARD
36206	PF - 901	ACHILLES BOOT	STANDARD
36206	PF - 902	STANDARD SHOULDER SUPPORT	STANDARD
36206	PF - 903	STANDARD VELPAU BANDAGE	S-M-L-XL-XXL- XXXL
36206	PF - 904	STANDARD CLAVICLE BANDAGE	S-M-L-XL
36206	PF - 905	STANDARD ELBOW SUPPORT	S-M-L-XL
41575	PF - 906	STANDARD ELBOW SUPPORT WITH EPICONDYLITIS	S-M-L-XL-XXL
41575	PF - 907	STANDARD WRIST SPLINT WITH THUMB SUPPORT	S-M-L-XL-XXL
41575	PF - 908	STANDARD WRIST SPLINT	S-M-L-XL-XXL
41575	PF - 909	STANDARD DE QUERVAIN SPLINT	S-M-L-XL-XXL
41575	PF - 910	STANDARD ABDOMINAL CORSET	S-M-L-XL-XXL
41575	PF - 911	STANDARD LUMBOSTAD CORSET (32CM)	S-M-L-XL-XXL
41575	PF - 912	STANDARD LUMBOSTAD CORSET (26CM)	S-M-L-XL-XXL
41575	PF - 913	STANDARD BASIC KNEE SUPPORT	STANDARD
41575	PF - 914	STANDARD PATELLA KNEE SUPPORT	STANDARD
36206	PF - 916	STANDARD PATELLA AND LIGAMENT KNEE SUPPORT	STANDARD
36206	PF - 915	STANDARD HINGED KNEE SUPPORT	S-M-L-XL-XXL
36206	PF - 917	STANDARD THIGH SUPPORT	S-M-L-XL-XXL
36206	PF - 918	STANDARD CALF SUPPORT	S-M-L-XL-XXL
41575	PF - 919	STANDARD CROSS ANKLE SUPPORT	STANDARD
11239	PF - 920	STANDARD SIMPLE ANKLE SUPPORT	MEDIUM 8-15- 30/ LARGE 7-15- 30

11239	PF - 570	STANDARD MALLEOL ANKLE SUPPORT	MINI 44-40/ MAXI 36/ JUNIOR 28
11239	PF - 571	STANDARD LIGAMENT ANKLE SUPPORT	MEDIUM-LARGE/ 14
33751	PF - 572	SOFT CERVICAL COLLAR	STANDARD
41435	PF - 573	CLAVICLE BANDAGE	S-M-L-XL-XXL
41472	PF - 574	ARM SLING NET	S-M-L-XL-XXL- XXXL
12099	PF - 575	ARM SLING SPONGE	S-M-L-XL
30878	PF - 576	ELBOW SUPPORT WITH PAD	T1-T2-T3-T4-T5- T6-T7
	PF - 577	POSTUREX CORSET	T1-T2-T3-T4-T5- T6-T7
	PF - 578	CHILD INGUINAL TRUSS (SINGLE SIDED)	T1-T2-T3-T4-T5- T6-T7
30878	PF - 579	CHILD INGUINAL TRUSS (DOUBLE SIDED)	T1-T2-T3-T4-T5- T6-T7
	PF - 580	MALLEOL ANKLE SUPPORT	T1-T2-T3-T4-T5- T6-T7
	PF - 581	SIMPLE ANKLE SUPPORT	T1-T2-T3-T4-T5- T6-T7
30878	PF - 582	WRIST SPLINT	T1-T2-T3-T4-T5- T6-T7
	PF - 588	PATELLA KNEE SUPPORT	T1-T2-T3-T4-T5- T6-T7
	PF - 583	DENIS BROWN SPLINT	T1-T2-T3-T4-T5- T6-T7
30878	PF - 584	DENIS BROWN SPLINT (ACTIVE)	T1-T2-T3-T4-T5- T6-T7
	PF - 585	DENIS BROWN BOOT	T1-T2-T3-T4-T5- T6-T7
	PF - 586	FREJKA ORTHOSIS	T1-T2-T3-T4-T5- T6-T7
41472	PF - 587	PAVLIC BANDAGE	STANDARD
41472	PF - 444	D.K.C ORTHOSIS	STANDARD
41472	PF - 445	IMMOBILIZER	STANDARD

36206	PF - 587	SILICONE INSOLE	STANDARD
36206	PF - 444	SILICONE INSOLE WITH ARCH SUPPORT	STANDARD
36206	PF - 445	SILICONE HEEL CUP	STANDARD
36206	PF - 446	SILICONE TOE SPREADER	STANDARD
36206	PF - 447	SILICONE BUNION	S-M-L-XL-XXL-XXXL
36206	PF - 448	CAST SHOE	S-M-L-XL
36206	PF - 451	HALLUX VALGUS SHOE	S-M-L-XL
41575	PF - 452	HALLUX VALGUS NIGHT SPLINT	S-M-L-XL-XXL
41575	PF - 453	STARFLEX INSOLE WITH ARCH SUPPORT	S-M-L-XL-XXL
41575	PF - 449	CORK INSOLE	S-M-L-XL-XXL
41575	PF - 450	SILICONE BREAST PROSTHESIS	S-M-L-XL-XXL
41575	PF - 333	BREAST BRA	S-M-L-XL-XXL
41575	PF - 334	SILICONE EXERCISE BALLS	S-M-L-XL-XXL
41575	PF - 335	SAND WEIGHT	S-M-L-XL-XXL
41575	PF - 336	EXERCISE BAND	STANDARD
41435	PV-113	ANTIEMBOLISM STOCKINGS-CALF	S-M-L-XL-XXL
41435	PV-114	ANTIEMBOLISM STOCKINGS-THIGH	S-M-L-XL-XXL
41435	PV-115K	ANTIEMBOLISM STOCKINGS-THIGH WITH WAIST FASTENING	S-M-L-XL-XXL
41435	PV-100	MEDICAL STOCKINGS-KNEE HIGH-OPEN TOE	1-2-3-4-5-6-7
41435	PV-101	MEDICAL STOCKINGS-KNEE HIGH-CLOSED TOE	1-2-3-4-5-6-7
41435	PV-102	MEDICAL STOCKINGS-THIGH HIGH-OPEN TOE	1-2-3-4-5-6-7
41435	PV-103	MEDICAL STOCKINGS-THIGH HIGH-CLOSED TOE	1-2-3-4-5-6-7
41435	PV-104	MEDICAL STOCKINGS-PANTYHOSE-OPEN TOE	1-2-3-4-5-6-7

41435	PV-105	MEDICAL STOCKINGS-PANTYHOSE-CLOSED TOE	1-2-3-4-5-6-7
41435	PV-106	MEDICAL STOCKINGS-KNEE HIGH-OPEN TOE	1-2-3-4-5-6-7
41435	PV-107	MEDICAL STOCKINGS-KNEE HIGH-CLOSED TOE	1-2-3-4-5-6-7
41435	PV-108	MEDICAL STOCKINGS-THIGH HIGH-OPEN TOE	1-2-3-4-5-6-7
41435	PV-109	MEDICAL STOCKINGS-THIGH HIGH-CLOSED TOE	1-2-3-4-5-6-7
41435	PV-110	MEDICAL STOCKINGS-PANTYHOSE-OPEN TOE	1-2-3-4-5-6-7
41435	PV-111	MEDICAL STOCKINGS-PANTYHOSE-CLOSED TOE	1-2-3-4-5-6-7
41435	PV-112	MEDICAL STOCKINGS-KNEE HIGH-OPEN TOE	1-2-3-4-5-6-7
41435	PV-113	MEDICAL STOCKINGS-KNEE HIGH-CLOSED TOE	1-2-3-4-5-6-7
41435	PV-114	MEDICAL STOCKINGS-THIGH HIGH-OPEN TOE	1-2-3-4-5-6-7
41435	PV-115	MEDICAL STOCKINGS-THIGH HIGH-CLOSED TOE	1-2-3-4-5-6-7
41435	PV-116	MEDICAL STOCKINGS-PANTYHOSE-OPEN TOE	1-2-3-4-5-6-7
41435	PV-117	MEDICAL STOCKINGS-PANTYHOSE-CLOSED TOE	1-2-3-4-5-6
41435	PV-300	MEDICAL STOCKINGS-TRAVEL SOCKS	1-2-3-4-5-6-7
41435	PL-01	ARM STOCKINGS FINGERS TO SHOULDERS WITH BAND	S-M-L-XL-XXL
41435	PL-02	ARM STOCKINGS WRIST TO SHOULDERS WITH BAND	S-M-L-XL-XXL
41435	PL-03	ARM STOCKINGS FINGERS TO SHOULDERS WITHOUT BAND	S-M-L-XL-XXL
41435	PL-04	ARM STOCKINGS WRIST TO SHOULDERS WITHOUT BAND	S-M-L-XL-XXL
41456	PF - 223	VISCO NECK PILLOW COMFORT	STANDARD
41456	PF - 225	VISCO CLASSIC NECK PILLOW COMFORT	STANDARD

41456	PF - 230	VISCO NECK PILLOW	STANDARD
41456	PF - 227	VISCO WAIST SUPPORT PILLOW	STANDARD
41456	PF - 231	VISCO TRAVELING PILLOW	STANDARD
41456	PF - 224	VISCO CLASSIC NECK PILLOW GEL COMFORT	STANDARD
41454	PF - 226	VISCO ANATOMIC WAIST SUPPORT PILLOW COMFORT	STANDARD
41454	PF - 228	VISCO ANATOMIC SITTING CUSHION COMFORT	STANDARD
41454	PF - 232	SPONGE WAIST SUPPORT CUSHION	STANDARD
41454	PF - 234	VISCO SEAT CUSHION (OPEN)	STANDARD
41454	PF - 237	VISCO REFLUX PILLOW	STANDARD
41454	PF - 229	VISCO SEAT CUSHION COMFORT	STANDARD
41454	PF - 235	SPONGE SEAT CUSHION	STANDARD
41454	PF - 236	VISCO SEAT CUSHION	STANDARD
41454	PF - 223	VISCO NECK PILLOW COMFORT	STANDARD
41454	PF - 225	VISCO CLASSIC NECK PILLOW COMFORT	STANDARD
41454	PF - 230	VISCO NECK PILLOW	STANDARD
41454	PF - 227	VISCO WAIST SUPPORT PILLOW	STANDARD
41454	PF - 231	VISCO TRAVELING PILLOW	STANDARD
41454	PF - 224	VISCO CLASSIC NECK PILLOW GEL COMFORT	STANDARD
41454	PF - 226	VISCO ANATOMIC WAIST SUPPORT PILLOW COMFORT	STANDARD
41454	PF - 228	VISCO ANATOMIC SITTING CUSHION COMFORT	STANDARD
41454	PF - 232	SPONGE WAIST SUPPORT CUSHION	STANDARD
41454	PF - 234	VISCO SEAT CUSHION (OPEN)	STANDARD
41454	PF - 237	VISCO REFLUX PILLOW	STANDARD

41454	PF - 229	VISCO SEAT CUSHION COMFORT	STANDARD
41454	PF - 235	SPONGE SEAT CUSHION	STANDARD
41454	PF - 236	VISCO SEAT CUSHION	STANDARD

ABDULBARİ HALICI
GENERAL MANAGER
İSTANBUL, TURKEY, 01.06.2023

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