



CERTIFICATE OF CONFORMITY



(2017/745/EU - Medical Devices Regulations)

MANUFACTURER'S NAME :HEGELİ ORTOPEDİK ÜRÜNLER SANAYİ VE
TİCARET LİMİTED ŞİRKETİ

ADDRESS :Selvitepe Mh. 2008 Cd. 203 Sk. No:15/A TURGUTLU - MANİSA -
TURKEY

BRANDS : ARMOR – BERCKS - SUPOR

PRODUCT SCOPE):

- Orthopedic and Surgical Corsets (Abdominal, Waist, Back, Neck Collar, Pregnancy Corset)
- Foot and Leg Health Products (Knee Pads, Calfs, Thermal Tights, Insoles, Heels, Rollers, Plaster Slippers, Hallux Valgus Shoes, Orthopedic Shoes, Orthopedic Slippers)
- Hand, Arm, Shoulder Health Products (Hand Splints, Arm Straps, Elbows, Thermoplastic Shoulder Supports)
- Ready-made Orthoses (Abdominal, Waist, Back, Neck, Leg, Hand, Arm, Shoulder)
- Breast Prosthesis and Straps (Silicone Breast) Protheses and Bras) –
- Walkers, Walking Supports, Collars, Wheelchairs,
- Shoulder Bandages , Foot and Hand Bandages ,
- Compression Stockings(Pregnant Tights, Thig high, Knee High) , Anti Embolism Stockings(Arm Belt, Thig high, Knee) , Lymphedema Stockings(Waist Belt, Thig high, Knee high and Pantyhose) , Lymphedema Sleeves(Shoulder Strap, Above Elbow) , Lymphedema Gloves (Open Toe, Long, Short)

I hereby declare and undertake that the product described above and attached to the mark is manufactured in accordance with the relevant EU directive and tested in accordance with the standards required by the directive, and will not harm all livingbeings, humans, animals, plants, the environment, life and property safety and harm.



CLASSIFICATION: Class 1, Annex IV(Annex II & Annex III) (without sterile and measuring function)

UDI-DI NUMBER: 868085313DT34HX - 869891504HG04Q3

STANDARDS

EN-ISO 13485:2016- Medical devices - Quality management systems - Legal regulation requirements

EN ISO 14971: 2019 Medical devices - Application of risk management to medical devices

Declaration of Conformity Start Date :01/06/2021

Place of Declaration :TURGUTLU/MANİSA

EU REPRESENTATIVE:

Company name (Company name type): FIZJOMED SPÓŁKA Z OGRANICZONĄ ODPOWIEDZIALNOŚCIĄ (main name)

Country : Poland

Registered office: UL. KRÓLOWEJ JADWIGI 281A, 30-234 KRAKÓW, Poland

Registration number: 0000562402

Company Type: Limited Liability Company

Business Register ID: KRS

EUID: PLKRS.0000562402

Manufacturer's Signature :

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ANNEX

	CERVICAL
ARN100	PLASTIC CERVICAL COLLAR-LENGTH ADJUSTABLE
ARN101	PLASTIC CERVICAL COLLAR-LENGTH ADJUSTABLE-WITH A CHIN SUPPORT
ARN102	CLASSICAL NELSON COLLAR-PLASTIZOTE
ARN102 A	CLASSICAL NELSON COLLAR-PLASTIZOTE WITH EXTRA COVER
ARN103	BASIC NECK COLLAR-SPONGE
ARN103 A	BASIC NECK COLLAR-SPONGE WITH EXTRA COVER
ARN103B	BASIC NECK COLLAR-SPONGE - WITH A RIGID SUPPORT
ARN104	CLASSICAL PHILADELPHIA COLLAR
ARN104B	CLASSICAL PHILADELPHIA COLLAR-WITH A TRACHEAL HOLE
ARN105	MINERVA ORTHOSIS
ARN108	WIREFRAME COLLAR
ARN109	SNOW MASK
ARVP01	ORTHOPEDIC VISCO NECK PILLOW
ARVP02	ORTHOPEDIC VISCO TRAVEL PILLOW
ARVP03	REFLUX PILLOW
ARVP04	CLASSICAL NECK PILLOW WITH GEL
	ARM&SHOULDER
ARM2800	NEOPRENE SHOULDER SUPPORT
ARM300B	ARMSLING WITH EXTRA BELT-GABARDINE-BASIC
ARM301B	ARMSLING WITH EXTRA BELT-LUXURY
ARM302	VELPEAU BANDAGE
ARM302P	SHOULDER IMMOBILIZER- STRONG
ARM302F	SHOULDER IMMOBILIZER - LIGHT
ARM303	PADDED ARMSLING-30 DEGREES
ARM303E	PADDED ARMSLING-45&60 DEGREES
ARM304	BASIC ARMSLING-MESH FABRIC
ARM311	CLAVICULA BANDAGE
ARM312	CLAVICULA BANDAGE -LIGHT
ARE1015	ANGLE ADJUSTABLE ELBOW CONTACTURE SPLINT
ARE2301	TENNIS PLAYER'S ELBOW SUPPORT
ARE2302	PADDED ELBOW SUPPORT
ARE2303	EPICONDYLITIS BANDAGE
ARE2303E	EPICONDYLITIS ORTHOSIS
	HAND, WRIST & FINGERS
ARH14	BOXER ATELLE
ARH15	BASIC THUMB SPLINT-WITH AN ALUMINUM THUMB SUPPORT
ARH15A	BASIC THUMB SPLINT-WITH VELCRO ADJUSTMENT
ARH16	HAND&WRIST SPLINT-SHORT
ARH19	HAND&WRIST SPLINT-LONG



ARH19FB	HAND&WRIST WITH LACES - MESH FABRIC
ARH19S	WRIST SPLINT-HIGHER STABILISATION
ARH19I	WRIST SPLINT- WITH LACES
ARH21	THUMB AND HAND SPLINT-WITH ALUMINUM SUPPORT ADJUSTMENT
ARH21A	THUMB AND HAND SPLINT-WITH VELCRO ADJUSTMENT
ARH21FB	THUMB AND HAND&WRIST WITH LACES - MESH FABRIC
ARH21S	THUMB AND WRIST SPLINT-HIGHER STABILISATION
ARH21I	HAND AND WRIST SPLINT-WITH LACES
ARH2600	SIMPLE NEOPRENE WRIST SUPPORT
ARH2601	NEOPRENE WRIST SUPPORT
ARH2603	NEOPRENE BANDAGE WRIST SUPPORT
ARH2605	NEOPRENE THUMB AND WRIST SUPPORT
ARH31	THERMOPLASTIC THUMB SPLINT
ARH32	THERMOPLASTIC ANTISPASTICITY SPLINT
ARH33	THERMOPLASTIC WRIST SPLINT
ARH34	THERMOPLASTIC THUMB AND WRIST SPLINT
ARH35	THERMOPLASTIC KLEINERT SPLINT
ARH40	THERMOPLASTIC DYNAMIC SPLINT
ARH94	MULLET FINGER SPLINT
ARH95	BASIC FINGER SPLINT
ARH96	PROTECTION SPLINT
ARH97	BASEBALL SPLINT
ARH98	FROG SPLINT
ARH99	BOUTONNIERE SPLINT
ARH100	SILICONE EXCERSIZE BALLS
	BACK, ABDOMEN & CHEST
ARC161	POSTURE HARNESS
ARC161S	SPINAL HARNESS
ARC162	POSTURE CORRECTOR
ARC2201	LUMBOSACRAL CORSET- NEOPRENE
ARC2202	LUMBOSACRAL CORSET WITH ADDITIONAL BELTS- NEOPRENE
ARC2203	ABDOMINAL BINDER- NEOPRENE
ARC260	LUMBOSACRAL CORSET-26CM BACK HEIGHT
ARC260K	LUMBOSACRAL CORSET WITH ADDITIONAL BELTS-26CM BACK HEIGHT
ARC260S	LUMBOSACRAL CORSET WITH PLASTIC SUPPORT
ARC320	LUMBOSACRAL CORSET-32CM BACK HEIGHT
ARC320S	LUMBOSACRAL CORSET WITH PLASTIC SUPPORT - 32 cm BACK HEIGHT
ARC320K	LUMBOSACRAL CORSET WITH ADDITIONAL BELTS-32CM BACK HEIGHT
ARC330K	DORSOLUMBAR CORSET
ARC340	TAYLOR TYPE CORSET



ARC420	ABDOMINAL BINDER
ARC420H	ABDOMINAL BINDER FOR COLOSTOMY BAG - 26 CM HIGH
ARC420K	ABDOMINAL BINDER WITH ADDITIONAL BELTS
ARC420S	ABDOMINAL BINDER FOR COLOSTOMY BAG - 16 CM HIGH
ARC421	STERNUM BELT-WITH PLASTIC INSERTS
ARC421A	STERNUM BELT-LUXURY
ARC421C	STERNUM BELT-WITH METAL INSERTS
ARC421G	STERNUM BELT-WITH METAL HANDLES
ARC422	UMBILICAL BELT-ADULT-16 CM HIGH
ARC422S	UMBILICAL BELT-ADULT-6 CM HIGH
ARC440	L.S.O. CORSET
ARC441	T.L.S.O. CORSET
ARC550	HYPEREXTENSION BELT-JEWETT
ARC550A	HYPEREXTENSION BELT-JEWETT-DYNAMIC
ARHS01	TRUSS-SINGLE
ARHS02	TRUSS-DOUBLE
ARC910	PREGNANCY BELT
ARBC01	ORTHOPEDIC BACK CUSHION
ARRC01	ORTHOPEDIC SITTING CUSHION - "O" SHAPED
ARRC02	ORTHOPEDIC SITTING CUSHION - "U" SHAPED
ARRC08	ORTHOPEDIC SITTING CUSHION
ARYK01	WOOL CORSET
ARG01	SILICONE BREAST PROSTHESIS SET
	LEG&HIPS
ARK1011	ANGLE ADJUSTABLE KNEE ORTHOSIS
ARK1011Y	ANGLE ADJUSTABLE KNEE ORTHOSIS - EXTENDIBLE
ARK1013	ANGLE ADJUSTABLE KNEE ORTHOSIS-NEOPRENE
ARK1014	FUNCTIONAL KNEE BRACE FOR ACL&PCL
ARK1045	KNEE IMMOBILIZER- 45 CM
ARK1051	HIP ABDUCTION ORTHOSIS
ARK1055	KNEE IMMOBILIZER- 55 CM
ARK1065	KNEE IMMOBILIZER- 65 CM
ARK1075	KNEE IMMOBILIZER- 75 CM
ARK2100	KNEE SUPPORT-CLOSED PATELLA
ARK2101	KNEE SUPPORT-PATELLAR SUPPORT
ARK2102	KNEE SUPPORT-PATELLAR&LIGAMENT SUPPORT-SHORT
ARK2103	KNEE SUPPORT-PATELLAR&LIGAMENT SUPPORT-LONG
ARK2103A	KNEE SUPPORT-PATELLAR&LIGAMENT SUPPORT-LONG-OPEN UPPER PART
ARK2104	KNEE SUPPORT-PATELLAR&LIGAMENT HINGED SUPPORT
ARK2104A	KNEE SUPPORT-PATELLAR&LIGAMENT HINGED SUPPORT-OPEN UPPER PART
ARK2104AK	KNEE SUPPORT-PATELLAR&LIGAMENT HINGED SUPPORT-FULLY OPEN FRONT



ARK2105	ELASTIC KNEE BANDAGE
ARK2106	KNEE SUPPORT-PADDED PATELLAR PROTECTION
ARK2109	KNEE SUPPORT-CRUCIAL LIGAMENT SUPPORT
ARK2110	PATELLAR TENDON BANDAGE
ARK2111	PATELLAR TENDON SUPPORT
ARK2112	ELASTIC KNEE BANDAGE
ARK2500	NEOPRENE THIGH SUPPORT
ARK2501	NEOPRENE CALF SUPPORT
ARK2503	NEOPRENE HIP SUPPORT
ARK2504	NEOPRENE HIP SUPPORT-WITH A PLASTIC HINGE
ARK2700	NEOPRENE SPORTMAN'S SHORTS
ARYD01	WOOL KNEE BANDAGE
	ANKLE
ARA101	PLASTIC ANKLE SUPPORT-INFLATABLE AIR PADDED
ARA102	PLASTIC ANKLE SUPPORT-SPONGE PADDED
ARA103	PLASTIC ANKLE SUPPORT -GEL PADDED
ARA11	REFLEX A.F.O.
ARA11A	DORSIFLEXION BANDAGE
ARA2214	ROM WALKER- FOR ACHILLES TENDON RUPTURES
ARA2215	ROM WALKER- ANGLE ADJUSTABLE
ARA2214S	ROM WALKER- FOR ACHILLES TENDON RUPTURES - SHORT
ARA2215S	ROM WALKER- ANGLE ADJUSTABLE - SHORT
ARA2400	ANKLE SUPPORT-BASIC-WITH VELCRO CLOSURE
ARA2400A	ANKLE SUPPORT-BASIC-WITH ZIPPER CLOSURE
ARA2401	ANKLE SUPPORT-MALLEOLAR PAD PROTECTION-WITH VELCRO CLOSURE
ARA2401A	ANKLE SUPPORT-MALLEOLAR PAD PROTECTION-WITH ZIPPER CLOSURE
ARA2402	ANKLE STABILIZER-WITH VELCRO CLOSURE
ARA2402A	ANKLE STABILIZER-WITH ZIPPER CLOSURE
ARA2403P	ANKLE STABILIZER – WITH LACES
ARA2405	ELASTIC ANKLE BANDAGE
ARA2406	FIGURE OF 8 BANDAGE
ARA51	RESTING A.F.O.
ARA51Y	RESTING A.F.O.-NEW GREY VERSION
	FOOT
ARF01	SILICONE INSOLES/FULL LENGTH-PREMIUM CLASS
ARF01K	SILICONE INSOLES/FULL LENGTH-FABRIC COATED
ARF01Y	SILICONE INSOLES -SPORTY - HIGHER ARC
ARF02	SILICONE INSOLES-3/4 LENGTH-PREMIUM CLASS
ARF03	SILICONE HEEL CUSHION-PREMIUM CLASS
ARF03Y	SILICONE HEEL CUSHION-WITH REMOVABLE AND SOFTNESS ADJUSTABLE PADS
ARF03YP	SILICONE HEEL CUSHION-WITH STICKY SURFACE AGAINST SLIPPING



ARF04	SILICONE METATARSAL PAD
ARF05	SILICONE ARC SUPPORT
ARF06	SILICONE TOE SEPARATOR
ARF07	STEEL INSOLES
ARF08	CORK INSOLES
ARF08Y	LEATHER INSOLES
ARF10	EPIN CALCANEI PAD
ARF11	CAST SHOES
ARF12	HALLUX VALGUS ATELLE - FOR NIGHT USE
ARF13	HALLUX VALGUS ATELLE - FOR DAY USE
ARF14	BUNION PROTECTOR
ARF14BM	BUNION PROTECTOR
ARF15	MEDIAL & LATERAL WEDGE - SILICONE
ARF16	HALLUX VALGUS SHOES
ARF17	TOE RING - SILICONE
ARF18	CUSHION FOR HAMMER TOE-SILICONE
ARF21	INSOLES - UCBL TYPE
	ARM'ALL
ARA5400	ANKLE BRACE -STANDARD
ARA5401	ANKLE BRACE - MALLEOLAR SUPPORT - STANDARD
ARA5402	ANKLE BRACE - LIGAMENT SUPPORT - STANDARD
ARH5015	DEQUERVAIN ATELLE - STANDARD-UNIVERSAL
ARH5019	WRIST SPLINT - STANDARD - UNIVERSAL
ARH5021	THUMB AND WRIST SPLINT - STANDARD - UNIVERSAL
ARK5100	CLOSED PATELLA KNEE BRACE - STANDARD
ARK5101	KNEE BRACE - PATELLAR SUPPORT - STANDARD
ARK5103	KNEE BRACE - SPRINGED LIGAMENT SUPPORT - STANDARD
ARK5104	KNEE BRACE - HINGED LIGAMENT SUPPORT - STANDARD
ARM5302	VELPEAU BANDAGE - STANDARD
ARM5300	ARMSLING -STANDARD
	ARM'O KNIT
ARH9019	KNITTED WRIST SUPPORT
ARA9400	KNITTED SIMPLE ANKLE SUPPORT
ARA9401	KNITTED ANKLE MALLEOLAR SUPPORT
ARA9403	KNITTED ACHILLES TENDON SUPPORT
ARC9202	KNITTED LUMBOSACRAL SUPPORT
ARE9301	KNITTED ELBOW SUPPORT
ARK9100	KNITTED SIMPLE KNEE SUPPORT
ARK9101	KNITTED PATELLA SUPPORT
ARK9103	KNITTED PATELLA AND LIGAMENT SUPPORT
ARK9104	KNITTED HINGED LIGAMENT SUPPORT



	ARM'O JEANS
ARJ260K	LUMBOSACRAL CORSET WITH ADDITIONAL BELTS-26CM BACK HEIGHT
ARJ320K	LUMBOSACRAL CORSET WITH ADDITIONAL BELTS-32CM BACK HEIGHT
ARJ161	POSTURE HARNESS
ARJ330K	DORSOLUMBAR CORSET
ARJ420	ABDOMINAL BINDER
ARJ910	PREGNANCY BELT
ARJ15	BASIC THUMB SPLINT-WITH AN ALUMINUM THUMB SUPPORT
ARJ19	HAND&WRIST SPLINT-LONG
ARJ19B	HAND&WRIST SPLINT-LONG - WITH LACES
ARJ21	THUMB AND HAND SPLINT-WITH ALUMINUM SUPPORT ADJUSTMENT
ARJ2301	TENNIS PLAYER'S ELBOW SUPPORT
ARJ2302	PADDED ELBOW
ARJ1011	ANGLE ADJUSTABLE KNEE ORTHOSIS
ARJ2100	KNEE SUPPORT - CLOSED PATELLA
ARJ2101	KNEE SUPPORT-PATELLAR SUPPORT
ARJ2102	KNEE SUPPORT-PATELLAR&LIGAMENT SUPPORT-SHORT
ARJ2103	KNEE SUPPORT-PATELLAR&LIGAMENT SUPPORT-LONG
ARJ2104	KNEE SUPPORT-PATELLAR&LIGAMENT HINGED SUPPORT
ARJ2106	KNEE SUPPORT-PADDED PATELLAR PROTECTION
ARJ301B	ARMSLING
ARJ311	CLAVICULA BANDAGE
ARJ2800	SHOULDER SUPPORT
ARJ302	VELPEAU BANDAGE
ARJ2400	ANKLE SUPPORT-BASIC-WITH VELCRO CLOSURE
ARJ2401	ANKLE SUPPORT-MALLEOLAR PAD PROTECTION-WITH VELCRO CLOSURE
ARJ2402	ANKLE STABILIZER-WITH VELCRO CLOSURE
ARJ103	NECK COLLAR - SPONGE
	ARM'O KIDS
ARA1400	PEDIATRIC ANKLE SUPPORT
ARA1401	PEDIATRIC MALLEOLAR ANKLE SUPPORT
ARC1161	PEDIATRIC POSTURE HARNESS
ARC1422	PEDIATRIC UMBILICAL BELT
ARDB01	DENNIS BROWN SPLINT
ARDB02	DENNIS BROWN BOOT
ARE1302	PEDIATRIC PADDED ELBOW BANDAGE
ARH1019	PEDIATRIC WRIST BANDAGE
ARHS1101	PEDIATRIC TRUSS-SINGLE
ARHS1102	PEDIATRIC TRUSS-DOUBLE
ARK1106	PEDIATRIC PADDED KNEE SUPPORT



ARM1300	PEDIATRIC ARMSLING-PRINTED FABRIC
ARM1304	PEDIATRIC ARMSLING-MESH FABRIC
ARM1311	PEDIATRIC CLAVICULA BANDAGE
ARN1103	PEDIATRIC SPONGE NECK COLLAR
ARPB01	PAVLIC HARNESS
ARFP01	FREJKA PILLOW
ARK1020	KNEE IMMOBILIZER- 20 CM
ARK1025	KNEE IMMOBILIZER- 25 CM
ARK1030	KNEE IMMOBILIZER- 30 CM
ARK1035	KNEE IMMOBILIZER- 35 CM
ARK1040	KNEE IMMOBILIZER- 40 CM
ARPB02	DDH ORTHOSIS
	ARM'O COMPRESS
	(20-30 mmHg)
ARS01	MEDICAL STOCKINGS-KNEE HIGH-OPEN TOE
ARS01A	MEDICAL STOCKINGS-KNEE HIGH-CLOSED TOE
ARS02	MEDICAL STOCKINGS-THIGH HIGH-OPEN TOE
ARS02A	MEDICAL STOCKINGS-THIGH HIGH-CLOSED TOE
ARS03	MEDICAL STOCKINGS-PANTYHOSE-OPEN TOE
ARS03A	MEDICAL STOCKINGS-PANTYHOSE-CLOSED TOE
	(30-40 mmHg)
ARS04	MEDICAL STOCKINGS-KNEE HIGH-OPEN TOE
ARS04A	MEDICAL STOCKINGS-KNEE HIGH-CLOSED TOE
ARS05	MEDICAL STOCKINGS-THIGH HIGH-OPEN TOE
ARS05A	MEDICAL STOCKINGS-THIGH HIGH-CLOSED TOE
ARS06	MEDICAL STOCKINGS-PANTYHOSE-OPEN TOE
ARS06A	MEDICAL STOCKINGS-PANTYHOSE-CLOSED TOE
	ANTIEMBOLISM
ARS07	ANTIEMBOLISM STOCKINGS-KNEE HIGH
ARS08	ANTIEMBOLISM STOCKINGS-THIGH
ARS09	ANTIEMBOLISM STOCKINGS-THIGH WITH WAIST FASTENING
	(18-22 mmHg)
ARS10	MEDICAL STOCKINGS-KNEE HIGH-OPEN TOE
ARS10A	MEDICAL STOCKINGS-KNEE HIGH-CLOSED TOE
ARS11	MEDICAL STOCKINGS-THIGH HIGH-OPEN TOE
ARS11A	MEDICAL STOCKINGS-THIGH HIGH-CLOSED TOE
ARS12	MEDICAL STOCKINGS-PANTYHOSE-OPEN TOE
ARS12A	MEDICAL STOCKINGS-PANTYHOSE-CLOSED TOE
	(14-18 mmHg)
ARS13A	MEDICAL STOCKINGS-KNEE HIGH-CLOSED TOE
ARS14A	MEDICAL STOCKINGS-THIGH HIGH-CLOSED TOE
ARS15A	MEDICAL STOCKINGS-PANTYHOSE-CLOSED TOE
ARS03H	MEDICAL STOCKINGS-PREGNANCY-OPEN TOE



	ARM AID
ARW01	ELBOW CRUTCHES-ALUMUNUM-PAIR
ARW02	CRUTCHES-ALUMINUM-PAIR
ARW03	WALKER-ALUMINUM
ARW03A	WALKER-ALUMINUM - PEDIATRIC
ARW04	FIXED ALUMINUM WALKER
ARW05	REVERSE WALKER
ARW05A	REVERSE WALKER- PEDIATRIC
ARW07	WALKER WITH TWO WHEELS
ARW08	CANE
ARW09	TRIPOD CANE
ARW09A	TRIPOD CANE WITH ELBOW HANDLES
ARW10	QUADRIPOD CANE
ARW10A	QUADRIPOD CANE WITH ELBOW HANDLES
ARW25	RUBBER TIPS - 19 MM DIAMETER
ARW26	RUBBER TIPS - 22 MM DIAMETER
ART01	COMMODE CHAIR-EKO
ART02	COMMODE CHAIR-LUXURY
ART04	PLASTIC RAISED TOILET SEAT
ART05	PLASTIC RAISED TOILET SEAT - WITH A COVER
ART07	SERUM HANGER- WITH WHEELS
ARP01	GAIT TRAINER - WAIST SUPPORTED
ARP02	GAIT TRAINER - WAIST AND CHEST SUPPORTED
ARP05	STANDING BOARD - BACK AND HIP SUPPORTED
	OTHERS
ARMP01	MATTRESS PROTECTOR

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