



**TETKO**

# CERTIFICATE

ATTESTATIONS OF CONFORMITY  
(EU) MDR 2017/745

Certificate Number: 030805

Certificate Owner : **HEGELİ ORTOPEDİK SAN. VE TİC. LTD.ŞTİ.**

**Selvilltepe OSB Mah. OSB 2008 Cad. No: 5 A**

**Turgutlu/ Manisa/ Türkiye**

**Product : Orthopedic Products ( Soft Ortez)  
and Orthopedic Support Products**

**Classification:** Non Steril, Disposable, Class 1- Annex 5

**Product Brand:**



**Reference Standards:**

EN ISO 14683, ISO EN 10993-1, EN ISO 14971

EN ISO 1041+A1, EN ISO 13982, EN ISO 1149-5

This certificate is issued voluntarily according to Medical Device Regulation (EU) MDR2017/745 .This is an acknowledgement that the listed product complies with principal protection provisions of the directive.

**Report - no.:BJ005.170601.1, 20RA.06199, 20.3.32229, 19.0.80573**

CE marking can be affixed on the product after the preparation of the necessary technical documentation and the conformity declaration as well as the production control guaranteed by the manufacturer and the provision of the other directive fulfilled if any



Certificate Date:01.06.2021

Expiry Date:31.05.2022

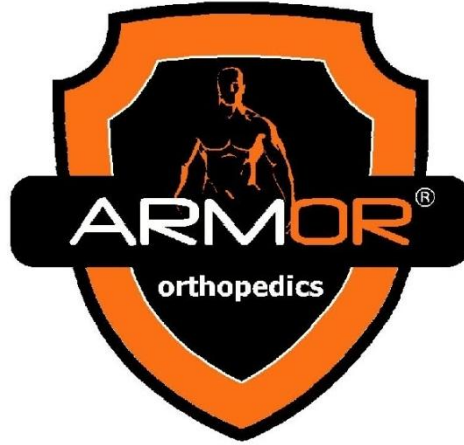
Period of Registration:1 Years

Executive Manager



*[Handwritten signature]*

# DECLARATION OF CONFORMITY



**EC Declaration of Conformity:** MEDICAL DEVICES DIRECTIVES (93/42/EEC) APPENDIX VII

**Manufacturer:** HEGELİ ORTOPEDİK ÜRÜNLER SAN. TİC. LTD. ŞTİ

**Manufacturer's address:** Cihangir Mah. Şehit Piyade Er Yavuz Bahar Sok.

No:4 Mirabbo Sanayi Sitesi D: Blok Kat:3

Ambarlı Avcılar İstanbul Turkey

**Device/s:** ORTHOPEDIC SUPPORT PRODUCTS

**Description:** MEDICAL DEVICE(S) THAT SUPPORT(S) THE HUMAN BODY EXTERNALLY.

**EC Product Class:** CLASS 1

**MEDICAL DEVICES DIRECTIVES (93/42/EEC) APPENDIX VII**

## **STANDARDS:**

EN 980: 2008: Graphical symbols for use in the labelling of medical devices.

EN ISO 14971: 2012 Medical devices. Application of risk management to medical devices

EN 1041: 2008 + A1: 2013 information supplied by the manufacturer of medical devices.

EN 14971: 2004: The risk analysis for medical devices.

## **Decleration OF CONFORMiTY**

**HEGELi ORTHOPEDiCS** declares that the medical device(s) listed on the attached Appendix A conform(s) to the relevant provisions of **the MDD 93/42/EEC MEDiCAL WRiTTEN DECREE COUNCiL** conditions.

**HEGELi ORTHOPEDiCS** confirms that no other application has been lodged with another notified body fort he same device related **QUALiTY MANAGEMENT SYSTEM iSO 9001:2008 and iSO 13485:2003**.

**HEGELi ORTHOPEDiCS** agrees to develop, implement and maintain a formally recognised Quality Management System to ensure continued adequacy and efficacy.

**HEGELi ORTHOPEDiCS** agrees to inform the appointed Notified Body of any planned and unplanned substantial change to the Qualilty Management System.

**HEGELi ORTHOPEDiCS** agrees to inform the appointed Notified Body of any planned or unplanned significant change to the Appendix A, including significant design change to the devices.

**Signed by the designated representative;**

**Name: Mr KEMAL ŞAHİN**

**Title: GENERAL MANAGER**

**HEGELİ ORTOPEDİK ÜRÜNLER  
ŞAN. TİC. LTD. ŞTİ.**  
Cihangir Mah. Şehit Piyade Er Yavuz Bahar Sokak  
Miyaböce San.Sit. No:4 D Blok K:2 Ambarlı-Avcılar/İST  
Tel.: (0212) 428 50 07 - 08 Fax.: (0212) 428 51 07  
Ticaret Sicil No: 281 948 4461 Ticaret Sicil No: 582033

**Date: 01/01/2019**

LABEL NAME	REF NO
SURGICAL MASK	SM001
LUMBOSTAD CORSET	ARC260K
LUMBOSTAD CORSET	ARC260
LUMBOSACRAL CORSET	ARC320K
LUMBOSACRAL CORSET WITH PLASTIC SUPPORT 26 cm BACK HEIGHT	ARC260S
LUMBOSACRAL CORSET WITH PLASTIC SUPPORT 32 cm BACK HEIGHT	ARC320S
LUMBOSACRAL CORSET	ARC320
DORSOLOMBAR CORSET	ARC330K
ABDOMINAL CORSET	ARC420
ABDOMINAL BINDER FOR A COLOSTOMY OPENING 26 CM HIGH	ARC420H
ABDOMINAL BINDER FOR A COLOSTOMY OPENING 16 CM HIGH	ARC420S
STERNUM CORSET	ARC421
PADDED STERNUM CORSET WITH STEEL INSERTS	ARC421C
UMBILICAL HERNIA BELT	ARC422
UMBILICAL BELT ADULT 6 CM HIGH	ARC422S
POSTUREX CORSET	ARC161
PREGNANCY CORSET	ARC910
POSTUREX CORSET WITH THERMOPLASTIC INSERTS	ARC161S
DORSOLUMBAR CORSET WITH THERMOPLASTIC INSERTS	ARC330S
TYLOR CORSET	ARC340
LUMBO SACRAL ORTHOSIS LSO	ARC440
THORACIC LUMBO SACRAL ORTHOSIS TLSO	ARC441
BASIC THUMB SPLINT WITH AN ALUMINUM THUMB SUPPORT	ARH15
THUMB SPLINT WITH VELCRO ADJUSTMENT	ARH15A
HAND SPLINT SHORT	ARH16
HAND SPLINT LONG	ARH19
THUMB AND HAND SPLINT WITH ALUMINUM SUPPORT ADJUSTMENT ARH21	ARH19S
WRIST SUPPORT	ARH19S
THUMB AND HAND SPLINT WITH A VELCRO ADJUSTMENT	ARH21A
SILICONE EXERCISE BALLS	ARH100
ARMSLING BASIC GABARDINE	ARM300
ARMSLING WITH EXTRA BELT GABARDINE BASIC	ARM300B
ARMSLING LUXURY	ARM301
ARMSLING WITH EXTRA BELT LUXURY	ARM301B
CLAVICULA BANDAGE	ARM311
VELPAU BANDAGE	ARM302
SHOULDER IMMOBILIZER	ARM302P
PADDED ARMSLING 30 DEGREES	ARM303
PADDED ARMSLING 45&60 DEGREES	ARM303E
ARMSLING BASIC MESH FABRIC	ARM304
KNEE SUPPORT PATELLAR SUPPORT	ARK2100
KNEE SUPPORT PATELLAR SUPPORT AEROTEX TYPE	ARK2100B
KNEE SUPPORT PATELLAR SUPPORT	ARK2101
KNEE SUPPORT PATELLAR SUPPORT AEROTEX TYPE	ARK2101B
KNEE SUPPORT PATELLAR&LIGAMENT SUPPORT SHORT	ARK2102

KNEE SUPPORT PATELLAR&LIGAMENT SUPPORT SHORT AEROTEX TYPE	ARK2102B
KNEE SUPPORT PATELLAR&LIGAMENT SUPPORT LONG	ARK2103
KNEE SUPPORT PATELLAR&LIGAMENT SUPPORT LONG AEROTEX TYPE	ARK2103B
KNEE SUPPORT PATELLAR&LIGAMENT SUPPORT LONG OPEN UPPER PART	ARK2103A
KNEE SUPPORT PATELLAR&LIGAMENT SUPPORT LONG OPEN UPPER PART AEROTEX TYPE	ARK2103AB
KNEE SUPPORT PATELLAR&LIGAMENT HINGED SUPPORT	ARK2104
KNEE SUPPORT PATELLAR&LIGAMENT HINGED SUPPORT AEROTEX TYPE	ARK2104B
KNEE SUPPORT PATELLAR&LIGAMENT HINGED SUPPORT OPEN UPPER PART	ARK2104A
KNEE SUPPORT PATELLAR&LIGAMENT HINGED SUPPORT OPEN UPPER PART AEROTEX TYPE	ARK2104AB
KNEE SUPPORT PATELLAR&LIGAMENT HINGED SUPPORT FULL OPEN FRONT	ARK2104AK
KNEE SUPPORT PATELLAR&LIGAMENT HINGED SUPPORT FULL OPEN FRONT AEROTEX TYPE	ARK2104AKB
KNEE SUPPORT PADDED PATELLAR PROTECTION	ARK2106
KNEE BRACE WITH ANGLE ADJUSTABLE HINGES	ARK2105
KNEE BRACE WITH ANGLE ADJUSTABLE HINGES OPEN TOP	ARK2105A
KNEE SUPPORT PADDED PATELLAR PROTECTION AEROTEX TYPE	ARK2106B
KNEE SUPPORT CRUCIAL LIGAMENT SUPPPORT	ARK2109
KNEE SUPPORT CRUCIAL LIGAMENT SUPPPORT AEROTEX TYPE	ARK2109B
PATELLAR TENDON BANDAGE	ARK2110
PATELLAR TENDON SUPPORT	ARK2111
ANKLE SUPPORT BASIC WITH VELCRO CLOSURE	ARA2400
ANKLE SUPPORT BASIC WITH ZIPPER CLOSURE	ARA2400A
ANKLE SUPPORT MALLEOLAR PAD PROTECTION WITH VELCRO CLOSURE	ARA2401
ANKLE SUPPORT MALLEOLAR PAD PROTECTION WITH ZIPPER CLOSURE	ARA2401A
ANKLE STABILIZER WITH VELCRO CLOSURE	ARA2402
ANKLE STABILIZER WITH ZIPPER CLOSURE	ARA2402A
FIGURE OF 8 BANDAGE	ARA2403
TENNIS PLAYER'S ELBOW SUPPORT	ARE2301
PADDED ELBOW SUPPORT	ARE2302
EPICONDYLITIS BANDAGE	ARE2303
PREMIUM EPYCONDYLITIS BANDAGE	ARE2303A
SIMPLE NEOPRENE WRIST SUPPORT	ARH2600
NEOPRENE WRIST SUPPORT	ARH2601
NEOPRENE BANDAGE WRIST SUPPORT	ARH2603
NEOPRENE THUMB SUPPORT	ARH2604
NEOPRENE THUMB AND WRIST SUPPORT	ARH2605
NEOPRENE LUMBOSACRAL CORSET	ARC2201
NEOPRENE LUMBOSACRAL CORSET WITH BELT	ARC2202
NEOPRENE ABDOMINAL CORSET	ARC2203
NEOPRENE SHOULDER SUPPORT	ARM2800
NEOPRENE THIGH SUPPORT	ARK2500
NEOPRENE CALF SUPPORT	ARK2501
NEOPRENE HIP SUPPORT	ARK2503
NEOPRENE SPORTMAN'S SHORTS	ARK2700
THERMOPLASTIC THUMB SPLINT	ARH31
THERMOPLASTIC ANTISPASTICITY SPLINT	ARH32
THERMOPLASTIC WRIST SPLINT	ARH33
THERMOPLASTIC THUMB AND WRIST SPLINT	ARH34
THERMOPLASTIC WRIST SPLINT WITH HOT&COLD GEL	ARH33S
THERMOPLASTIC DYNAMIC HAND SPLINT	ARH40

THERMOPLASTIC AFO REFLEX	ARA11
DORSIFLEXION BANDAGE	ARA11A
THERMOPLASTIC KLEINERT ATELLE	ARH35
THERMOPLASTIC AFO RESTING	ARA51
THERMOPLASTIC AFO RESTING SUPREME	ARA51Y
THERMOPLASTIC HIP ABDUCTION ORTHOSIS	ARK1051
PLASTIC CERVICAL COLLAR LENGTH ADJUSTABLE	ARN100
PLASTIC CERVICAL COLLAR LENGTH ADJUSTABLE WITH A CHIN SUPPORT	ARN101
BASIC NECK COLLAR SPONGE	ARN103
BASIC NECK COLLAR SPONGE WITH AN ADDITIONAL COVER	ARN103A
CLASSICAL NELSON COLLAR PLASTIZOTE	ARN102
PREMIUM NELSON COLLAR PLASTIZOTE WITH A COVER	ARN102A
CLASSICAL PHILADELPHIA COLLAR	ARN104
PREMIUM PHILEDELPHIA COLLAR WITH A COVER	ARN104A
CLASSICAL PHILEDELPHIA COLLAR WITH A TRACHEAL HOLE	ARN104B
MINERVA ORTHOSIS	ARN105
THERMOPLASTIC RIGID CERVICAL COLLAR WITH A COVER	ARN107
WIRE FRAME CERVICAL COLLAR	ARN108
PLASTIC ANKLE SUPPORT AIRCAST	ARA101
PLASTIC ANKLE SUPPORT SPONGE PADDED	ARA102
PLASTIC ANKLE SUPPORT GEL PADDED	ARA103
CORK INSOLE	ARF08
CORK INSOLE LUXURY	ARF08Y
STARLIGHT INSOLES	ARF09
EPIN CALCUNUS PAD	ARF10
FREJKA PILLOW	ARFP01
UCBL INSOLES	ARF21
ANGLE ADJUSTABLE KNEE ORTHOSIS	ARK1011
ANGLE ADJUSTABLE KNEE ORTHOSIS EXTENDIBLE	ARK1011Y
ANGLE ADJUSTABLE KNEE ORTHOSIS NEOPRENE	ARK1013
ANGLE ADJUSTABKE KNEE ORTHOSIS DYNAMIC	ARK1014
ROM WALKER ACHILLES TENTON ORTHOSIS	ARA2214
ROM WALKER ANGLE ADJUSTABLE ANKLE ORTHOSIS	ARA2215
CAST SLIPPERS	ARF11
CAST SHOES	ARF11Y
BUTONIER SPLINT	ARH99
FROG SPLINT	ARH98
BASEBALL SPLINT	ARH97
PROTECTION SPLINT	ARH96
BASIC FINGER SPLINT	ARH95
MULLET FINGER SPLINT	ARH94
SILICONE INSOLES/FULL LENGNTH PREMIUM CLASS	ARF01
SILICONE INSOLES/SPORTY HIGHER ARCH	ARF01Y
SILICONE INSOLES 3/4 LENGTH PREMIUM CLASS	ARF02
SILICONE HEEL CUSHION PREMIUM CLASS	ARF03
SILICONE HEEL CUSHION WITH REMOVABLE AND SOFTNESS ADJUSTABLE PADS	ARF03Y
SILICONE HEEL CUSHION WITH STICKY SURFACE AGAINST SLIPPING	ARF03YP
SILICONE METATARSAL PAD	ARF04
SILICONE ARC SUPPORT	ARF05
SILICONE TOE SEPARATOR	ARF06

STEEL INSOLES	ARF07
HALLUX VALGUS NIGHT SPLINT	ARF12
HALLUX VALGUS DAY SPLINT	ARF13
SILICON BUNION PROTECTOR	ARF14
SILICON BUNION PROTECTOR W/ TOE SEPERATOR	ARF14BM
SILICON MEDIAL AND LATERAL ARCH WEDGE	ARF15
HALLUX VALGUS SHOE	ARF16
SILICON TOE RING	ARF17
SILICON HAMMER TOE CREST	ARF18
JEWETT HYPEREXTENSION CORSET	ARC550
JEWETT HYPEREXTENSION CORSET PREMIUM	ARC550A
ANGLE ADJUSTABLE ELBOW CONTACTURE SPLINT SOFT	ARE1015
KNEE IMMOBILIZER	ARK1040
KNEE IMMOBILIZER	ARK1045
KNEE IMMOBILIZER	ARK1050
KNEE IMMOBILIZER	ARK1055
KNEE IMMOBILIZER	ARK1060
KNEE IMMOBILIZER	ARK1065
KNEE IMMOBILIZER	ARK1075
ELBOW IMMOBILIZER	ARE25
ORTHOPEDIC BACK CUSHION	ARBC01
ORTHOPEDIC RING CUSHION	ARRC01
ORTHOPEDIC RING CUSHION U SHAPED	ARRC02
HERNIA SUPPORT SINGLE	ARHS01
HERNIA SUPPORT DOUBLE	ARHS02
ORTHOPEDIC VISCO NECK PILLOW	ARVP01
ORTHOPEDIC VISCO TRAVEL PILLOW	ARVP02
REFLUX PILLOW WEDGE PILLOW	ARVP03
VISCO PILLOW GEL PADDED	ARVP04
WOOL CORSET	ARYK01
WOOL KNEE BANDAGE	ARYD01
SUSPENSORY	ARHS03
ARM'O KIDS PEDIATRIC ARMSLING MESH FABRIC	ARM1304
ARM'O KIDS PEDIATRIC ARMSLING PRINTED FABRIC	ARM1300
ARM'O KIDS PEDIATRIC CLAVICULA BANDAGE	ARM1311
ARM'O KIDS PEDIATRIC PADDED ELBOW BANDAGE	ARE1302
ARM'O KIDS PEDIATRIC POSTURE HARNESS	ARC1161
ARM'O KIDS PEDIATRIC WRIST BANDAGE	ARH1019
ARM'O KIDS PEDIATRIC PADDED KNEE SUPPORT	ARK1106
ARM'O KIDS PEDIATRIC ANKLE SUPPORT	ARA1400
ARM'O KIDS PEDIATRIC MALLEOLAR ANKLE SUPPORT	ARA1401
RM'O KIDS PEDIATRIC PEDIATRIC UMBILICAL TRUSS	ARC1422
ARM'O KIDS PEDIATRIC SPONGE NECK COLLAR	ARN1103
ARM'O KIDS PEDIATRIC KNEE IMMOBILIZER	ARK1025
ARM'O KIDS PEDIATRIC KNEE IMMOBILIZER	ARK1030
ARM'O KIDS PEDIATRIC KNEE IMMOBILIZER	ARK1035
ARM'O KIDS PEDIATRIC DENNIS BROWNE ATELLE	ARDB01
ARM'O KIDS PEDIATRIC DENNIS BROWNE BOOTS	ARDB02
PEDIATRIC INGUINAL HERNIA SUPPORT SINGLE	ARHS1101
PAVLIK HARNESS	ARPB01

DDH ORTHOSIS	ARPB02
PEDIATRIC INGUINAL HERNIA SUPPORT DOUBLE	ARHS1102
RM"ALL" ONE SIZE KNEE SUPPORT	ARK5100
ARM"ALL" ONE SIZE KNEE SUPPORT PATELLA SUPPORT	ARK5101
ARM"ALL" ONE SIZE KNEE SUPPORT LIGAMENT SUPPORT	ARK5103
ARM"ALL" ONE SIZE KNEE SUPPORT HINGED KNEE SUPPORT	ARK5104
ARM"ALL" ONE SIZE TENNIS PLAYER'S ELBOW SUPPORT	ARE5301
ARM"ALL" ONE SIZE UNIVERSAL WRIST SUPPORT	ARH5019
ARM"ALL" ONE SIZE UNIVERSAL THUMB SUPPORT	ARH5015
ARM"ALL" ONE SIZE UNIVERSAL WRIST AND THUMB SUPPORT	ARH5021
ARM"ALL" ONE SIZE ANKLE SUPPORT	ARA5400
ARM"ALL" ONE SIZE ANKLE SUPPORT SILICONE SUPPORT	ARA5401
ARM"ALL" ONE SIZE ANKLE SUPPORT LIGAMENT SUPPORT	ARA5402
ARM"ALL" ONE SIZE BACK SUPPORT	ARC5202
ARM"ALL" ONE SIZE BANDAGE WRIST SUPORT	ARH5603
ARM"ALL" ONE SIZE ARMSLING	ARM5300
ARM"ALL" ONE SIZE VELPEAU BANDAGE	ARM5302
ARM"ALL" ONE SIZE FIGURE OF 8 BANDAGE	ARA2406
ARM'O KNIT KNITTED KNEE SUPPORT	ARK9100
ARM'O KNIT KNITTED PATELLAR SUPPORT	ARK9101
ARM'O KNIT KNITTED PATELLA AND LIGAMENT SUPPORT SUPPORT	ARK9103
ARM'O KNIT KNITTED HINGED LIGAMENT SUPPORT	ARK9104
ARM'O KNIT KNITTED BACK SUPPORT	ARC9202
ARM'O KNIT KNITTED ELBOW SUPPORT	ARE9301
ARM'O KNIT KNITTED ANKLE SUPPORT SIMPLE	ARA9400
ARM'O KNIT KNITTED ANKLE MALLEOLAR SUPPORT	ARA9401
ARM'O KNIT KNITTED ANKLE LIGAMENT SUPPORT	ARA9402
ARM'O KNIT KNITTED ACCHILLES TENDON SUPPORT	ARA9403
ELBOW CRUTCHES ALUMUNUM PAIR	ARW01
CRUTCHES ALUMINUM PAIR	ARW02
WALKER ALUMINUM	ARW03
WALKER IRON PIPE	ARW04
REVERSE WALKER IRON PIPE	ARW05
PEDIATRIC REVERSE WALKER IRON PIPE	ARW06
WALKER WITH 2 WHEELS IRON PIPE	ARW07
WALKING STICK CANE ALUMINUM	ARW08
TRIPOD WALKING STICK IRON PIPE	ARW09
QUADRIPOD WALKING STICK IRON PIPE	ARW10
QUADRIPOD WALKING STICK CANADIAN GRIP IRON PIPE	ARW10A
GAIT TRAINER IRON PIPE HIP SUPPORTED	ARP01
GAIT TRAINER IRON PIPE HIP & CHEST SUPPORTED	ARP02
STANDING TABLE IRON PIPE	ARP03
STANDING TABLE WITH BACK SUPPORT IRON PIPE	ARP04
STANDING TABLE WITH BACK SUPPORT AND A SEAT IRON PIPE	ARP05
CRUTCH TIPS	ARW25
PEDIATRIC WALKER	ARW03A
PEDIATRIC REVERSE WALKER	ARW05A
TRIPOD CANE WITH ELBOW HANDLE	ARW09A
RAISED TOILET WITH A LID	ART05
SERUM HANGER	ART07



COMMODE CHAIR EKO	ART01
COMMODE CHAIR LUXURY	ART02
TOILET ASCENDER WITHOUT LID	ART04
MEDICAL STOCKINGS CALF OPEN TOE	ARS01
MEDICAL STOCKINGS CALF CLOSED TOE	ARS01A
MEDICAL STOCKINGS THIGH OPEN TOE	ARS02
MEDICAL STOCKINGS THIGH CLOSED TOE	ARS02A
MEDICAL STOCKINGS PANTY OPEN TOE	ARS03
MEDICAL STOCKINGS PANTY CLOSED TOE	ARS03A
MEDICAL STOCKINGS CALF OPEN TOE	ARS04
MEDICAL STOCKINGS CALF CLOSED TOE	ARS04A
MEDICAL STOCKINGS THIGH OPEN TOE	ARS05
MEDICAL STOCKINGS THIGH CLOSED TOE	ARS05A
MEDICAL STOCKINGS PANTY OPEN TOE	ARS06
MEDICAL STOCKINGS PANTY CLOSED TOE	ARS06A
MEDICAL STOCKINGS KNEE HIGH OPEN TOE	ARS10
MEDICAL STOCKINGS KNEE HIGH CLOSED TOE	ARS10A
MEDICAL STOCKINGS KNEE HIGH OPEN TOE	ARS13
MEDICAL STOCKINGS KNEE HIGH CLOSED TOE	ARS13A
MEDICAL STOCKINGS THIGH HIGH OPEN TOE	ARS11
MEDICAL STOCKINGS THIGH HIGH OPEN TOE	ARS14
MEDICAL STOCKINGS PANTYHOSE OPEN TOE	ARS12
MEDICAL STOCKINGS PANTYHOSE CLOSED TOE	ARS12A
MEDICAL STOCKINGS PANTYHOSE CLOSED TOE	ARS15A
ANTIEMBOLESTOCKINGS CALF	ARS07
ANTIEMBOLESTOCKINGS THIGH	ARS08
ANTIEMBOLESTOCKINGS THIGH WITH WAIST FASTENING	ARS09

**HEGELİ ORTOPEDİK ÜRÜNLER**  
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# QUALITY MANAGEMENT SYSTEM CERTIFICATE

Universal GmbH

This certificate is granted to the organization,

**HEGELI ORTOPEDIK URUNLER SAN. VE TIC. LTD. STI.**

Selvittepeosh Mah. 2008. Cad. No:5/A Turgutlu/MANISA/TURKEY

by review of RA2-3078 numbered report for the scope

to certify that a management system in accordance with  
standard's clauses is established and being implemented

**DIN EN ISO 9001:2015**

Certificate No : QMS 0115 004134

Original Certification Date : 19.01.2015

Issue / Revised Date : 15.01.2021

Expiry Date : 18.01.2022

Certification Period : 3 years (1<sup>st</sup> year)



Deutsche  
Akkreditierungsstelle  
D-ZM-15058-01-00

Universal GmbH



# MEDICAL QUALITY MANAGEMENT SYSTEM CERTIFICATE

Universal GmbH

This certificate is granted to the organization,

**HEGELI ORTOPEDIK URUNLER SAN. VE TIC. LTD. STI.**

Selvittepeosb Mah. 2008. Cad. No:5/A Turgutlu/MANISAA/TURKEY

by review of RA2-3078 numbered report for the scope

to certify that a management system in accordance with standards clauses is established and being implemented

**DIN EN ISO 13485:2016**

Certificate No :MDMS 0115 004134

Original Certification Date : 19.01.2015

Issue / Revised Date : 15.01.2021

Expiry Date : 18.01.2022

Certification Period : 3 years (1<sup>st</sup> year)



*J. M. B. U. G.*

Universal GmbH