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EU DECLARATION OF CONFORMITY

Company Name	Variteks Ortopedi Sanayi A.Ş.
Address	Ferhatpaşa Sb. Mahallesi Menekşe Sokak Variteks Blok No:3, İç Kapı No: Z1, 34540 Çatalca, İstanbul / TÜRKİYE
Phone	+90 212 544 30 50
Web Site	https://www.variteks.com/
Basic UDI	8692195VO00001VP
Classification Rule / (MDR EU 2017 / 745)	Class I, Rule I (Annex VIII according to EU 2017 / 745)
Single Register Number (SRN)	TR-MF-000026919
Brand	Variteks, Nexus, Supersport, Nitgo

GMDN Code	EMDN Code	Ref. No	Product Scope
10284: Pressure bandage, non-latex, non-sterile, single use	M0303010101: Elastic fixing bandages, non-adhesive, extensible in one direction	406	Elastic Bandage (6 cm)
		408	Elastic Bandage (8 cm)
		410	Elastic Bandage (10 cm)
		412	Elastic Bandage (12 cm)
		415	Elastic Bandage (15 cm)
41038: Orthotic helmet	T020699: Medical Use Face Masks (Excluding Personal Protective Equipment -PPE) - Other	260	Nose Guard Mask
11095: Foot Cushion	V080399: Medical Cushions - Other	541	Silicone Insole with Arch Support
		542	Silicone Full Length Insole
		543	Silicone ¾ Length Insole
		544	Silicone Heel Support
		549	Silicone Forefoot Insole
		550	Silicone Bunion Shield
		551	Silicone Metatarsal Pad with Ring
		553	Silicone Toe Crest with Loop (right-left)
		591	Silicone Insole with Arch Support
		593	Silicone ¾ Length Insole
		594	Silicone Heel Spur
41573: Cervical spine		565	Silicone Heel Spur (Siliconed Bunion Protection)
		651	Visco Orthopedic Neck Pillow

cushion		652	Visco Orthopedic Neck Pillow Classic
		656	Visco Orthopedic Travel Pillows
		676	Travel pillow
41057: Lumbar cushion		658	Visco Anatomic Back Cushion (with belt)
		657	Visco Back Cushion (with belt)
34982: Stool cushion		659	Visco Seating Donut Cushion "D" Form
		662	Visco Wheelchair Seating Cushion
		663	Visco Coccyx Seating Cushion
		679	Polyurethane Seating Donut Cushion "D" Form
34981: Perineal/coccygeal cushion		664	Gluteal Seating Cushion
43445: Thoracolumbosacral spine orthosis, rigid	Y060306: Thoracolumbar Orthoses	140	Elastic Dorsolomber Corset (height adjustable)
		162	TX Dorsolomber Corset
		110	Dorsolomber Corset
33031: Lumbar spine orthosis		118	Clavicle Bandage
		138	Posturex (Clavicle) Corset
		180	Dorso-Plus DorsoLomber Corset
41030: Lumbosacral spine orthosis, pendulous abdomen support	Y060308: Lumbosacral Spine Orthoses	121	Hooked Under Breast – Below knee
		122	Hooked Under Breast – Above knee
		123	Hooked Waist-Below Knee (reinforced)
		124	Hooked Panty Corset
		132	Postoperative Abdominal Corset (28 cm)
41029: Lumbosacral spine orthosis, hernia/ptosis support		133	Postoperative Abdominal Corset (20 cm)
		134	Elastic Abdominal Hernia Corset (20cm)
		136	Colostomy Corset
		142	Abdolumbar Corset
33031: Lumbar spine orthosis		101	Hooked Waist Corset
		112	Judo Waist Corset
41442: Lumbosacral spine orthosis, flexible		889	Waist Support
		890	Practical Waist Support
		111	Lumbosacral Corset
33031: Lumbar spine orthosis		461	Knitted Lumbosacral Corset
		139	Elastic Pregnancy Corset
41443: Lumbosacral spine orthosis, corset, hernia		181	Sacro-plus Back Brace Pro
		185	Sacro-plus Back Brace
41031: Toracolumbosacral spine orthosis, waist corset, flexible	Y060309: Thoracolumbosacral Spine Orthoses	130	Elastic Dorsolomber Corset
		137	Rib Belt Corset

41039: Cervical spine collar, reusable	Y060312: Cervical Spine Orthoses	201	Support Collar
		202	Chin Support Collar
		203	Soft Collar
		204	Nelson Collar
		205	Philadelphia Collar
		206	Nelson Collar With Chin Support
		207	Soft Nelson Collar
		208	UNI-COLLAR Soft
		210	Philadelphia Tracheostomy Collar
		250	Minevra Collar
35409: Spinal hernia truss	Y060406: Abdominal hernia supports	603	Elastic Truss For Child
30883: Abdominal hernia truss, single use		601	Elastic Truss
		602	Elastic Truss (double)
		604	Child Umbilicus
41456: Finger Orthosis	Y060603: Fingers orthoses	545	Silicone Toe Spreader
16210: Hand/finger splint, single-use		546	Silicone Toe Separator
		547	Silicone Ring
		548	Silicone Toe Cap
		550	Silicone Bunion Shield
		332	Curved Finger Splint
		333	Finger Protector
		334	Finger Cot
		335	Frog Splint
		336	Ring Splint Finger Splint
		331	Baseball Splint
42050: Finger protector, reusable		340	Rhizoplus Thumb Brace
41458: Wrist orthosis	Y060609: Wrist (Forearm) orthoses	881	Wrist Band
		882	Wrist Support
		826	Wrist Brace
41459: Wrist/hand orthosis	Y060612: Wrist-hand orthoses	165	TX Wrist Brace Splint
		301	Wrist Brace Splint
		307	Elastic Wrist Brace Splint
		309	Flexi Wrist Brace Splint
		311	Static Wrist Brace Splint
		319	Flexi Wrist Splint with Thumb Grip
		825	Wrist Brace Splint
		879	Wrist Brace Splint

41044: Wrist/hand/finger stable-position orthosis	Y060613: Wrist-hand-finger orthoses	306	Wrist Splint with Thumb Grip
41456: Finger Orthosis		880	Thumb Brace
		305	Thumb Grip
41458: Wrist orthosis		722	Wrist & Thumb Support
41459: Wrist/hand orthosis		465	Knitted Wrist Splint
		462	Knitted Wrist Support
12101: Shoulder immobilizer, reusable	Y060621: Shoulder orthoses	460	Knitted Shoulder Support
41465: Shoulder Support		842	Shoulder Support
41466: Shoulder/Elbow Support	Y060627: Shoulder-elbow - wrist orthoses	304	Shoulder Support Bandage (Velpau)
41467: Orthosis, shoulder/elbow/wrist		302	Arm Sling
		302-K	Arm Sling with Belt
		303	Arm Sling (sponge)
		312	Neoprene Arm Sling
		313	Active Arm Sling
		314	Active Arm Sling With Air Pad
		315	Flexi Arm Sling
		323	Practical Arm Sling
10284: Pressure bandage, non-latex, non-sterile, single-use	Y061203: Orthoses, Foot(Including Insoles and Insert)	564	Siliconed Metatarsal Support
41575: Orthotic insoles		501	Metal Foot Support
30999: Ankle/foot orthosis		455	Knitted Achilles Tendon Support
		456	Knitted Malleol Ankle Support
		474	Plantar Fasciitis Support With Silicone
		510	Hallux Valgus Night Support
		511	Hallux Valgus Night Splint
		814	Ankle Stabilizer (Air Pad)
		815	Ankle Stabilizer (Sponge Pad)
		475	Arc Support with Silicone
		476	Bunion Socks with Silicone
36206: Ankle/foot orthosis	Y06120601: Passive Ankle - Foot Orthoses	724	Ankle Support
		801	Elastic Ankle Brace
		824	Ankle Brace with Bandage



		827	Ankle Support with Spiral Stays
		844	Ankle Brace with Support
		864	AFO (foot guard)
		887	Ankle Support
		897	Ankle Brace with Flexible Stays
		863	Drop Foot Support
		864	AFO Foot Guard
		865	Reflex AFO
		811	Pediatric Walker
		812	Air Walking Boot Short
		813	Air Walking Boot Standard
41065: Knee Orthosis	Y061209: Knee Orthoses	320	Knee Immobilizer
		453	Knitted Flexible Knee Support
		454	Knitted Hinged Knee Brace
		725	Knee Support
		803	Elastic Knee Brace
		804	Knee Brace
		806	Knee Brace (long)
		822	Knee Brace With Patella Support
		823	Knee Brace With Spiral Stays
		828	Hinged Stabilizing Knee Brace
		833	Articulated Knee Stabilizer
		834	Crossed Ligament Knee Support
		884	Knee Support
		886	Patella Band
		860	Genu Recurvatum Knee Cage
		858	Hinged Stabilizing Knee Brace (Height Adjustable)
		898	Hinged Stabilizing Knee Brace
		885	Open Knee Support
36228: Orthosis (brace) hip	Y061215: Hip Orthoses (Including Abduction Orthoses)	188	Abduction Corset
		119	Pavlic Bandage
41542: Leg/Knee	Y061218: Hip-Knee-	888	Thigh Support

Cushion	Ankle-Foot Orthoses	892	Calf Support
41478: Orthosis, hip/knee		723	Calf Support
41070: Orthosis, knee/ankle/foot		802	Elastic Tendon Brace
10481: Surgical brassiere	Y061219: Chest-Lumb- Sacral-Hip-Knee-Ankle-Foot Orthoses	577	Bra For Breast Prothesis
41053: Elbow Orthosis	Y061812: Elbow Disarticulation Prostheses	160	TX Epicondylitis Bandage
		458	Knitted Elbow Support (with silicone)
		721	Elbow Support
		760	Epicondylitis Bandage
		829	Tennis Elbow Support
		849	Elbow Support with Silicone
		859	Elbow Rom Orthosis
		883	Epicondylitis Bandage
		330	Epicondylitis Bandage
35676: Breast prosthesis, external	Y063018: External Breast Prostheses	570	Silicone Breast Prothesis (Pear - Symmetrial)
34200: Finger/hand Exerciser	Z12069099: Various Physiotherapy and Rehabilitation Instruments - Other	560	Silicopad Silicone Hand Rehabilitation Ball
30927: Finger/hand assistive training device		350	Hand Rehabilitation Kit
30927: Finger/hand assistive training device		355	Hand Rehabilitation Device

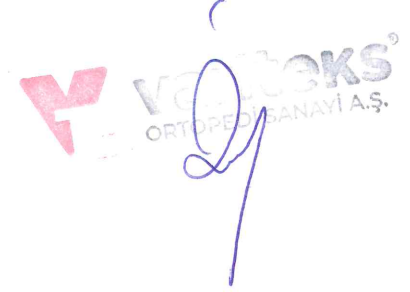
Related Standards

EU 2017 / 745 (MDR)	Medical Device Regulation
ISO 13485:2016	Quality Management System for Medical Device
EN ISO 14971: 2019	Medical devices - Risk management for medical devices Implementation
EN ISO 24971: 2020	Guidance for the Implementation of the Medical Device Risk Regulation
EN ISO 15223-1: 2016	Medical devices - Medical device labelling to be provided, symbols to be used with labels and information - Part 1: General requirements
EN 20417:2020	Information provided by the medical device manufacturer
IEC 62366-1:2015	Medical devices - Part 1: Application of usability techniques to medical devices
ISO 10993-1: 2018	Biological assessment of medical devices - Part 1: Assessment and testing within a risk management process
EN 20471:2020	Information provided by the medical device manufacturer
IEC 62366-1:2015	Medical devices - Part 1: Application of usability techniques to medical devices

MDCG 2020-7	Post-Marketing Clinical Follow-up (PMCF) Plan Template
MDCG 2020-8	Post-Market Clinical Follow-up (PMCF) Evaluation Report Template

Bedri Okan ÖZTÜRKATALAY
Chairman of the Board of Directors

İstanbul / TÜRKİYE
18.11.2024



Variteks
ORTOPEDI SANAYİ A.Ş.