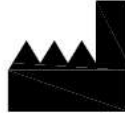


Declaration of Conformity (v.20210817)

1. **Manufacturer:** United Sports Brands - McDavid
Address: 11488 Slater Avenue
 Fountain Valley CA 92708
 Ph.: +1 (952) 767.2329
 URL: www.unitedspb.com
 United States
 SRN: US-MF-000008428

On product labels printed as:P



United Sports Brands – Shock Doctor Inc.
 11488 Slater Avenue
 Fountain Valley CA 92708 (USA)
 Ph.: +1 (952) 767.2329
 URL: www.unitedspb.com
 SRN: NL-MF-000008428

2. **EU Authorized Representative:** QNET B.V.
 P.. Box 10110, NL-5060 GA Oisterwijk
 Kantstraat 19, NL-5076 NP Haaren
EAR@Medical-risk.com

On the product printed as:



QNET B.V.
 Po.O. Box 10110, NL-5060 GA Oisterwijk
 Kantstraat 19, 5076 NP Haaren
 URL: EAR@ce-mark.com
 SRN: NL-AR-000002695

3. **UK Responsible Person:** QNET LTD.
 Livingstone House
 309 Harrow Road
 Wembley, Middlesex HA9 6BD

4. The product(s) described above are in conformity with:

<u>The product(s) described conform with:</u>	<u>Document No.</u>	<u>Title</u>	<u>Edition / Date of issue</u>
<MDD>	L 169; 93/42/EEC	Medical Device Directive, Annex VII	1993-06-14
<MDR>	OJ L 117 5.5.2017	Medical Device Regulations EU/2017/745	April 5, 2017

5. **Products (Note: If there are multiple products within one family group, provide list in Table One)**
- Product Name:** PERFORMANCE SPORT THERAPY™ – See REF list for details
Trade Name: PERFORMANCE SPORT THERAPY™ – See REF list for details
GMDN code: See reference list
CND classes: t.b.d.
Intended Purpose: (61652) A non-sterile sleeve intended to be externally worn on a limb to provide support or local pressure to a part of the body, especially a joint, for various preventative/therapeutic applications (e.g., support soft tissue injuries) while enabling movement.
- Basic UDI-DI:** See reference list
Risk Classification (EU Annex VIII): Per MDR Annex VIII, Risk Class: I based on rule 1.
Conformity Procedure: MDR Annexes: I, II, and III.
Relevant CE-Certificate(s): Self-Declaration
EU Notified Body: Not Applicable

6. **Official EU Language(s)** English, German, Hungarian, Czech, Dutch, Finnish, French, Danish, Slovakian, Greek, Italian, Norwegian, Polish, Russian, Spanish, Swedish

Declaration of Conformity in accordance with EN ISO/IEC 17050-1:2004



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7. Additional information:

The following harmonized standards have either been referred to or been complied with in part or in full as relevant:

EN 1041:2018+A1:2013	Information supplied by the manufacturer of medical devices.
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices.
IEC 62366-1:2015+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices.
ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes.
ISO 14971:2019	Medical devices - Application of risk management to medical devices.
ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03).

8. Date of first CE marking: January, 2016.

9. CIBG-code: NL-CA002-xxxx

'I declare that above mentioned medical device complies with the MDR-EU 2017/745.'

Signature Jay Turkbaz



Revision Date:
January 2016

Description:
Initial declaration

August 17, 2021

Textual correction

Drs Ton Denissen Digitally signed by Drs Ton Denissen
Date: 2022.10.12 19:34:32 +02'00'

Declaration of Conformity in accordance with EN ISO/IEC 17050-1:2004



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DECLARATION OF CONFORMITY, REF List

REF	SPORTMED™ Product Details
	Basic UDI-DI: 0029369MD4102AR
MD4102-01-32	Runners Therapy: Shin Splint Sleeve Code: 61652
MD4102-01-33	Runners Therapy: Shin Splint Sleeve Code: 61652
MD4102-01-34	Runners Therapy: Shin Splint Sleeve Code: 61652
MD4102-01-35	Runners Therapy: Shin Splint Sleeve Code: 61652
	Basic UDI-DI: 0029369MD441J4
MD441-01-32	Calf Sleeve GMDN Code: 61652
MD441-01-33	Calf Sleeve GMDN Code: 61652
MD441-01-34	Calf Sleeve GMDN Code: 61652
MD441-01-35	Calf Sleeve GMDN Code: 61652
	Basic UDI-DI: 0029369MD471JD
MD471-01-32	Level 1 Thigh Sleeve GMDN: 61652
MD471-01-33	Level 1 Thigh Sleeve GMDN: 61652
MD471-01-34	Level 1 Thigh Sleeve GMDN: 61652
MD471-01-35	Level 1 Thigh Sleeve GMDN: 61652
MD475-01-00	Groin Wrap / adjustable GMDN: 61652, Basic UDI-DI: 0029369MD474JM
MD478RSS-01-00	Thigh Wrap / adjustable GMDN: 61652, Basic UDI-DI: 0029369MD478JT
	Basic UDI-DI: 0029369MD479JV
MD479-01-32	Neoprene Shorts w/ adjustable drawstring GMDN: 61652
MD479-01-33	Neoprene Shorts w/ adjustable drawstring GMDN: 61652
MD479-01-34	Neoprene Shorts w/ adjustable drawstring GMDN: 61652
MD479-01-35	Neoprene Shorts w/ adjustable drawstring GMDN: 61652
MD479-01036	Neoprene Shorts w/ adjustable drawstring GMDN: 61652
	Basic UDI-DI: 00293694305R7T
4305R-BK-XS/S	Phantom 3+ Ankle Brace Code: 61652
4305R-BK-M/L	Phantom 3+ Ankle Brace Code: 61652
4305R-BK-X/XXL	Phantom 3+ Ankle Brace Code: 61652
	Basic UDI-DI: 0029369MD510HW
MD510-01-32	Knee Sleeve / elastic GMDN: 61652
MD510-01-33	Knee Sleeve / elastic GMDN: 61652
MD510-01-34	Knee Sleeve / elastic GMDN: 61652
MD510-01-35	Knee Sleeve / elastic GMDN: 61652
	Basic UDI-DI: 0029369MD511HY
MD511-01-32	Ankle Sleeve / elastic GMDN: 61652
MD511-01-32	Ankle Sleeve / elastic GMDN: 61652
MD511-01-32	Ankle Sleeve / elastic GMDN: 61652
MD511-01-33	Ankle Sleeve / elastic GMDN: 61652

Declaration of Conformity in accordance with EN ISO/IEC 17050-1:2004



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MD512-01-34	Basic UDI-DI: 0029369MD512J2
MD512-01-35	Elbow Sleeve / elastic GMDN: 61652
MD512-01-34	Elbow Sleeve / elastic GMDN: 61652
MD512-01-35	Elbow Sleeve / elastic GMDN: 61652
	Basic UDI-DI: 0029369MD513J4
MD513-01-10	Wrist Sleeve / adjustable / elastic GMDN: 61652
MD513-01-30	Wrist Sleeve / adjustable / elastic GMDN: 61652
	Basic UDI-DI: 0029369MD5115B9
MD5115-01-32	Ankle Sleeve / 4-way elastic w/ gel buttresses GMDN: 61652
MD5115-01-33	Ankle Sleeve / 4-way elastic w/ gel buttresses GMDN: 61652
MD5115-01-34	Ankle Sleeve / 4-way elastic w/ gel buttresses GMDN: 61652
MD5115-01-35	Ankle Sleeve / 4-way elastic w/ gel buttresses GMDN: 61652
	Basic UDI-DI: 0029369MD514J6
MD514-01-32	Thigh Sleeve / elastic GMDN: 61652
MD514-01-33	Thigh Sleeve / elastic GMDN: 61652
MD514-01-34	Thigh Sleeve / elastic GMDN: 61652
MD514-01-35	Thigh Sleeve / elastic GMDN: 61652
	Basic UDI-DI: 0029369MD5115B9
MD5115-01-33	Ankle Sleeve / 4-way elastic w/ gel buttresses GMDN: 61652
MD5115-01-34	Ankle Sleeve / 4-way elastic w/ gel buttresses GMDN: 61652
MD5115-01-35	Ankle Sleeve / 4-way elastic w/ gel buttresses GMDN: 61652
	Basic UDI-DI: 0029369MD5116BB
MD5116-01-32	Knee Sleeve/4-way elastic w/ gel buttress GMDN: 61652
MD5116-01-33	Knee Sleeve/4-way elastic w/ gel buttress GMDN: 61652
MD5116-01-34	Knee Sleeve/4-way elastic w/ gel buttress GMDN: 61652
MD5116-01-35	Knee Sleeve/4-way elastic w/ gel buttress GMDN: 61652
	Basic UDI-DI: 0029369MD5122B6
MD5122-01-32	Ankle Sleeve / 4-way elastic w/ figure-8 straps GMDN: 61652
MD5122-01-33	Ankle Sleeve / 4-way elastic w/ figure-8 straps GMDN: 61652
MD5122-01-34	Ankle Sleeve / 4-way elastic w/ figure-8 straps GMDN: 61652
MD5122-01-35	Ankle Sleeve / 4-way elastic w/ figure-8 straps GMDN: 61652
	Basic UDI-DI: 0029369MD5125BC
MD5125-01-32	Knee Sleeve / 4-way elastic w/ gel buttress GMDN: 61652
MD5125-01-33	Knee Sleeve / 4-way elastic w/ gel buttress GMDN: 61652
MD5125-01-34	Knee Sleeve / 4-way elastic w/ gel buttress GMDN: 61652
MD5125-01-35	Knee Sleeve / 4-way elastic w/ gel buttress GMDN: 61652
	Basic UDI-DI: 0029369MD5130B5
MD5130-01-32	Elbow sleeve 4 way elastic w/ gel buttress GMDN: 61652
MD5130-01-33	Elbow sleeve 4 way elastic w/ gel buttress GMDN: 61652
MD5130-01-34	Elbow sleeve 4 way elastic w/ gel buttress GMDN: 61652
MD5130-01-35	Elbow sleeve 4 way elastic w/ gel buttress GMDN: 61652
	Basic UDI-DI: 0029369MD5135BF
MD5135-01-32	Freelastics plantar fascia sleeve GMDN: 61652
MD5135-01-33	Freelastics plantar fascia sleeve GMDN: 61652

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MD5135-01-34 MD5135-01-35	Freelastics plantar fascia sleeve GMDN: 61652 Freelastics plantar fascia sleeve GMDN: 61652
MD5140-01-32 MD5140-01-33 MD5140-01-34 MD5140-01-35	Basic UDI-DI: 0029369MD5140B8 Knee sleeve 4 way seamless elastic: GMDN: 61652 Knee sleeve 4 way seamless elastic GMDN: 61652 Knee sleeve 4 way seamless elastic GMDN: 61652 Knee sleeve 4 way seamless elastic GMDN: 61652
MD5113-01-32 MD5113-01-33 MD5113-01-34 MD5113-01-35	Basic UDI-DI: 0029369MD5113B5 Knee sleeve 4 way elastic GMDN: 61652 Knee sleeve 4 way elastic GMDN: 61652 Knee sleeve 4 way elastic GMDN: 61652 Knee sleeve 4 way elastic GMDN: 61652
MD5136-01-32 MD5136-01-33 MD5136-01-34 MD5136-01-35	Basic UDI-DI: 0029369MD5136BH Elbow sleeve 4 way elastic GMDN: 61652 Elbow sleeve 4 way elastic GMDN: 61652 Elbow sleeve 4 way elastic GMDN: 61652 Elbow sleeve 4 way elastic GMDN: 61652
MD5221-01-31 MD5221-01-32 MD5221-01-33 MD5221-01-34 MD5221-01-35	Basic UDI-DI: 0029369MD5221B9 Hyperblend Ankle sleeve GMDN: 61652 Hyperblend Ankle sleeve GMDN: 61652 Hyperblend Ankle Sleeve GMDN: 61652 Hyperblend Ankle sleeve GMDN: 61652 Hyperblend Ankle sleeve GMDN: 61652
MD5223-01-31 MD5223-01-32 MD5223-01-33 MD5223-01-34 MD5223-01-35	Basic UDI-DI: 0029369MD5223BD Hyperblend Ankle sleeve w/ stay GMDN: 61652 Hyperblend Ankle sleeve w/ stay GMDN: 61652 Hyperblend Ankle sleeve w/ stay GMDN: 61652 Hyperblend Ankle sleeve w/ stay GMDN: 61652 Hyperblend Ankle sleeve w/ stay GMDN: 61652
MD5225-01-31 MD5225-01-32 MD5225-01-33 MD5225-01-34 MD5225-01-35	Basic UDI-DI: 0029369MD5225BH Hyperblend Ankle sleeve w/ stay & vertical strap GMDN: 61652 Hyperblend Ankle sleeve w/ stay & vertical strap GMDN: 61652 Hyperblend Ankle sleeve w/ stay & vertical strap GMDN: 61652 Hyperblend Ankle sleeve w/ stay & vertical strap GMDN: 61652 Hyperblend Ankle sleeve w/ stay & vertical strap GMDN: 61652
MDX609-01-32 MDX609-01-33 MDX609-01-34 MDX609-01-35	Basic UDI-DI: 0029369MDX609KM McDavid X dual layer compression calf sleeves GMDN: 61652 McDavid X dual layer compression calf sleeves GMDN: 61652 McDavid X dual layer compression calf sleeves GMDN: 61652 McDavid X dual layer compression calf sleeves GMDN: 61652
1122R.MDA-GR-S/M 1122R.MDA-GR-L/XL	Basic UDI-DI: 54300001122R.MDA4T Ankle Compression Knit Sleeve w/ Gel Buttress GMDN: 61652 Ankle Compression Knit Sleeve w/ Gel Buttress GMDN: 61652

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1224R.MDA-GR-L/XL
1224R.MDA-GR-S/M

Basic UDI-DI: 54300001224R.MDA68

Knee Compression Knit Sleeve Gel ButtressGMDN: 61652
Knee Compression Knit Sleeve Gel ButtressGMDN: 61652

1226R.MDA-GR-L/XL
1226R.MDA-GR-S/M

Basic UDI-DI:54300001226R.MDA72

Knee Comp.Knit Sleeve buttress & stays GMDN: 61652
Knee Comp.Knit Sleeve buttress & stays GMDN: 61652

1322R,MDA-GR-S/M
1322R.MDA-GR-L/XL

Basic UDI-DI: 54300001322R.MDA5Z

Elbow Comp. Knit Sleeve Gel Buttress GMDN: 61652
Elbow Comp. Knit Sleeve Gel Buttress GMDN: 61652

1522R.MDA-GR-L/XL
1522R.MDA-GR-S/M

Basic UDI-DI: 54300001522R.MDA77

Wrist Comp. Support GMDN: 61652
Wrist Comp. Support GMDN: 61652

