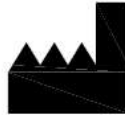


Declaration of Conformity (v.20210817)

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: Elbow Orthosis (41053). An externally supplied orthopaedic appliance to encompass the elbow joint to support, align, prevent, or correct deformities/injuries or to improve function of the elbow. This is a reusable device.
- 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



Declaration of Conformity (v.20210817)

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 19:32:26 +02'00'



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

Declaration of Conformity (v.20210817)

DECLARATION OF CONFORMITY, REF List

REF	SPORTMED™ Product Details
	Basic UDI-DI: 0029369MD485JQ
MD485-01-32	Elbow Support w/ Strap GMDN Code: 41053
MD485-01-33	Elbow Support w/ Strap GMDN Code: 41053
MD485-01-34	Elbow Support w/ Strap GMDN Code: 41053
MD485-01-35	Elbow Support w/ Strap GMDN Code: 41053
	Basic UDI-DI: 0029369MD489JY
MD489-01-32	Elbow Support w/ pads GMDN: 41053
MD489-01-33	Elbow Support w/ pads GMDN: 41053
MD489-01-34	Elbow Support w/ pads GMDN: 41053
	Basic UDI-DI: 0029369MD481JG
MD481-01-32	Elbow Support GMDN Code: 41053
MD481-01-33	Elbow Support GMDN Code: 41053
MD481-01-34	Elbow Support GMDN Code: 41053
MD481-01-35	Elbow Support GMDN Code: 41053
	Basic UDI-DI: 0029369MD486JS
MD486-01-00	Elbow Strap / adjustable GMDN Code: 41053
	Basic UDI-DI: 0029369MDX601K5
MDX601-01-32	McDavid X Dual layer compression arm sleeves GMDN: 41053
MDX601-01-33	McDavid X Dual layer compression arm sleeves GMDN: 41053
MDX601-01-34	McDavid X Dual layer compression arm sleeves GMDN: 41053
MDX601-01-35	McDavid X Dual layer compression arm sleeves GMDN: 41053
	Basic UDI-DI: 0029369MDX607KH
MDX607-01-32	McDavid X dual layer compression elbow sleeves GMDN: 41053
MDX607-01-33	McDavid X dual layer compression elbow sleeves GMDN: 41053
MDX607-01-34	McDavid X dual layer compression elbow sleeves GMDN: 41053
MDX607-01-35	McDavid X dual layer compression elbow sleeves GMDN: 41053

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

