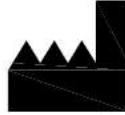


# Declaration of Conformity (v.20210817)

1. Manufacturer: United Sports Brands - McDavid  
 Address: 11488 Slater Avenue  
 Fountain Valley CA 92708  
 Ph.: +1 (952) 767.2329  
 URL: [www.unitedspb.com](http://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](http://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](mailto: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](mailto: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: Shoulder immobilizer, reusable (12101). A non-rigid device used to temporarily immobilize or limit abduction of the shoulder joint to support healing of an injury. It will typically consist of layered fabric, straps, buckles, fasteners. 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 19:33:31 +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
MD462-01-33 MD462-01-34 MD462-01-35	<b>Basic UDI-DI: 0029369MD462JC</b> Shoulder Support GMDN Code: 12101 Shoulder Support GMDN Code: 12101 Shoulder Support GMDN Code: 12101
MD463-01-32 MD463-01-32 MD463-01-32	<b>Basic UDI-DI: 0029369MD463JE</b> Shoulder Wrap GMDn: 12101 Shoulder Wrap GMDn: 12101 Shoulder Wrap GMDn: 12101

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

