

CERTIFICATE OF CONFORMITY

Ref. No.: HT22040145M001

Applicant : Yangzhou Hongwei Sports Products Co., Ltd.
No. 99, Fuming Industrial Concentration District,
Yangzhou, Jiangsu, China

Manufacturer : Same as applicant

Product : Sports Safety

Trademark : SHIWEI

Model(s) : See Annex

CONFORMITY DETAILS		
REGULATION	APPLICABLE STANDARD(S)	TEST REPORT NO.
(EU) 2017/745 (MDR)	EN ISO 15223-1:2021 EN ISO 20417:2021 EN ISO 14971:2019 EN ISO 10993-1:2020 EN ISO 10993-5:2009 EN ISO 10993-10:2013	TR22040145.M001

We confirm that the Technical Documentation for the above-mentioned Product complies with the applicable requirements of the Regulation (EU) 2017/745.

Referring to the intended use, we have conducted with successful results the review of the Manufacturer's Technical Documentation of the certified product according to the above-mentioned Directive and the applicable standards.

This Certificate is issued under the following conditions:

- 1) The Manufacturer's Technical Documentation, as required for Class I Devices (non-sterile, without measuring function, non-reusable surgical instrument), has been reviewed according to Annexes II and III (Article 52, point 7).
- 2) It applies only to the above-mentioned Medical Devices.
- 3) The Manufacturer is obligated to assure conformity of all the Medical Devices of the respective model to the type assessed by the mean of this Certificate.
- 4) Any significant changes in the Design or Process used to manufacture the Product, or revision to the Directives or standards referred above may require a special audit by us.

TOM KWOK
Authorized Signature
Date of Issue: 08 April 2022

After fulfilling the relevant EU Legislation Requirements, the Manufacturer shall affix to each Medical Device, CE Marking according to the above example. This certificate expires upon the withdrawal of one of the above-mentioned standards.

Hwatest Compliance Services Co., Ltd.
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ANNEX TO CERTIFICATE

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Product Model:

- 1. Waist support belt**
- 2. Back support**
- 3. Knee brace**
- 4. Ankle brace**
- 5. Elbow brace**
- 6. Wrist brace**
- 7. Hand brace**
- 8. Arm belt**
- 9. Shoulder brace**
- 10. Maternity belt**
- 11. Postpartum belt**
- 12. Neck brace**
- 13. Sports gloves**
- 14. Sports socks**
- 15. Gel cushion**
- 16. Foot separator**
- 17. Acupuncture massage mat**

This Annex is part of a full certificate and should be read in conjunction with it.



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