



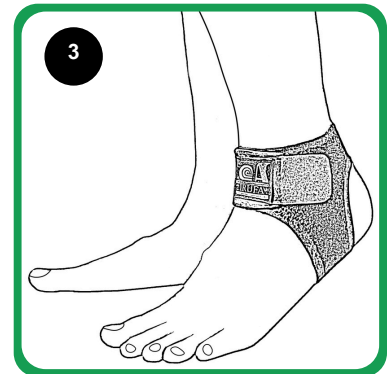
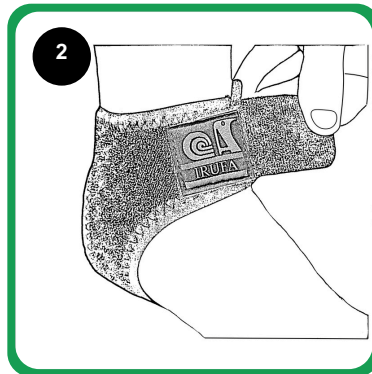
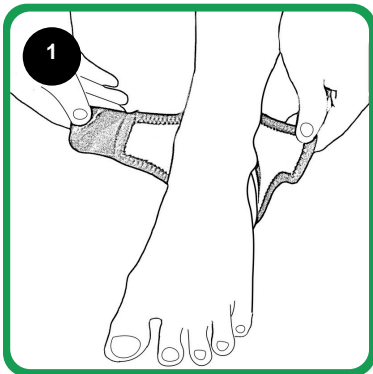
Ankle Brace -Technical Data Sheet

INTENDED USE

The IRUFA Ankle Brace is designed to support and stabilize the ankle joint, helping reduce the risk of sprains and injuries during physical activities. Made from Spacer Fabric, it provides compression and cushioning to alleviate discomfort and promote healing. This brace is ideal for individuals with weak or injured ankles, enabling them to stay active while minimizing the risk of further injury.



INSTRUCTIONS FOR USE

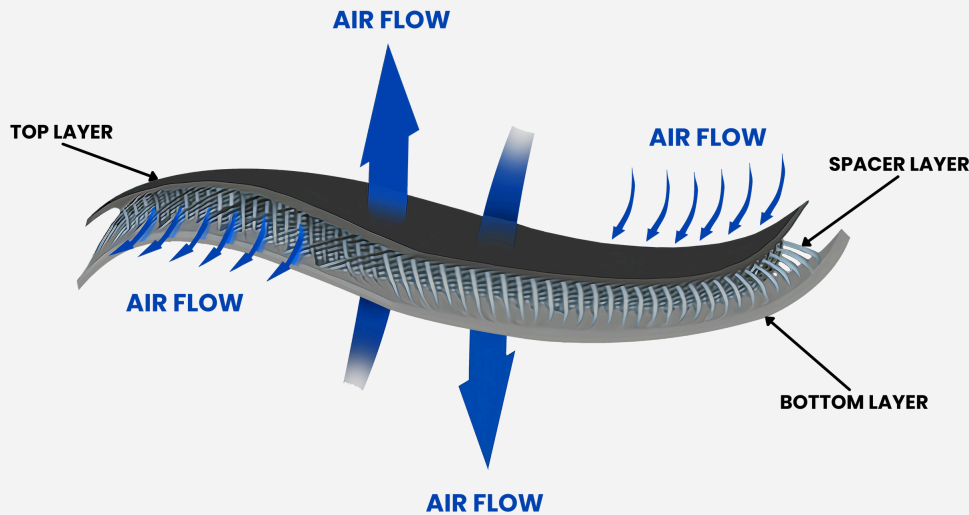


COMPOSITION

Made by Spacer Fabric (Nylon, Polyester, spandex)



PRODUCT CHARACTERISTICS



The effects of the Irufa Heel & Elbow Protector are made possible due to the use of Spacer Fabric:

- 3D breathable
- Latex-free
- Wicking
- Machine washable
- Suitable for continuous use (24 hours)
- Air cushion function to help reduce pressure and prevent decubitus ulcers.

PRECAUTIONS AND RECOMMENDATIONS

- The use by more than one patient may cause cross-infection.
- Do not use the product on injured skin.
- Do not use the product if it is contaminated, dirty, or evidently deteriorated.

LAUNDERING INSTRUCTIONS

- Can be washed by machine in cold or warm water.
- Chlorine bleaching is not advised, as it weakens the fabric and shortens the product's lifespan.
- Avoid excessive heat, as this may cause shrinkage.





Irufa Industrial Group

Next Generation Medical Supports Manufacturer

STORAGE AND SHELF-LIFE

- Keep away from sunlight.
- Keep dry.
- Shelf-life: 5 years.

IN COMPLIANCE WITH

- Directive 93/42/EEC of the Council, Directive 2007/47/EC of the European Parliament, and Regulation (EU) 2017/745 of the European Parliament and of the Council.
- Class I, non-sterile (as per Annex IX of Directive 93/42 and Annex VIII of Regulation 745/2017).
- Enterprise certified by ISO 13485 and ISO 9001.



CERTIFICATE



The Governing Board of
ARES International Certification Co., Ltd.
Hereby Grants To:

Irufa Industrial Group Co., Ltd.
No.32, Alley 182, Cheng-Ping 7th St., Tainan, R.O.C.

Has been assessed and found to be in accordance with the requirements of standard detailed below
ISO 13485:2016

Scope
Manufacture of Sports & Medical Support, Cold hot therapy wraps

Certificate No.: ARES/TW/I2308050M Certificate Issue Date: 2023-08-10
Expiration Date: 2026-08-09

The time interval between each surveillance audit and the last on-site audit shall not exceed 12 months, and the organization must obtain "surveillance audit approval notification" issued by ARES to ensure the validity of the certificate.



Authorized by:



IAS ACCREDITED
Management Systems
Certification Body
ACC NO. MSCB - 171



Member of Multilateral Recognition Arrangement



ARES International Certification Co., Ltd.
No.12-2, Ln. 187, Wenping Rd., Anping Dist., Tainan City 708, Taiwan
TEL / 06-295 9696 (Rep. Line) FAX / 06-295 9667
www.ares-registration.com



Certificate of Registration

This certificate has been awarded to

Irufa Industrial Group Co., Ltd.
No.32, Alley 182, Cheng-Ping 7th St., Tainan, Taiwan (R.O.C.)

In recognition of the organization's Quality Management System which complies with

ISO 9001:2015

The scope of activities covered by this certificate is defined below
Manufacture and Sales of Sporting and Medical Supports, Mattress, Insoles, Exercise Pants and Cold Hot Wraps

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
14 October 2021	5	15 October 2025	4
16 September 2022	6	16 October 2025	3

For detailed explanation for the data fields above, refer to <http://www.urs-holdings.com/regs-and-regulations>

Issued by:






On behalf of the Schemes Manager