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Patient Information for Use document:
DMO® Custom Vest & Leotard



www.dmorthotics.com

Our products

Our Custom Made Dynamic Movement Orthoses® use a soft, flexible elastomeric fabric that ensures a close fit and creates compression forces to enhance proprioceptive feedback. This base fabric is light-weight, breathable and strong.

This is combined with reinforcement panels made using a powernet material to provide strength and stability where required improving posture and biomechanical alignment.

Our made to measure orthoses work by using strategically placed reinforcements, which position the body into improved postural alignment. This new biomechanical state combined with enhanced proprioception, stimulates and adjusts the neuro-sensory system, training muscles to work with improved tone, strength and performance. DMO®'s help both adults and children manage the physical effects of their neurological, musculoskeletal and genetic conditions.

DMO® Custom products are individually made-to-measure, and all fastenings, openings and reinforcements are individually prescribed according to the functional needs and preferences of each individual patient.

Get in Touch

To find out more about our DMO® Product ranges, contact your local DMO® provider or distributor or DM Orthotics directly to find out who that is. Email: admin@dmorthotics.com visit: www.dmorthotics.com call: +44 (0) 1209 219205

How we intend our products to be used by patients

DM Orthotics custom-made orthotic devices are intended for the **exclusive use of a single specific patient** to support and correct posture and joint alignment. It should not be worn by any other person who it was not individually measured and prescribed for.

All DM Orthotics custom made orthoses, are medical devices as defined by the EU MDR (2017/745) and conform to the regulations according to Annex XIII of the EU MDR.

Date of Issue

Our custom made devices are manufactured to a specific prescription and will be issued with a date of manufacture on the accompanying statement form that is sent with your product. This is for the end user to keep for their records.

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Wear instructions

Follow the care instructions carefully. By taking care of your orthosis you will **prolong its wear and prevent damage.**

DO

- Put the orthosis on and off as advised by your therapist/ supplier. See website: www.dmorthotics.com/productcare
- Take care when putting it on and taking it off, follow the instructions in this booklet carefully– pulling it on and off roughly and long finger nails can cause damage.
- It is important to build up wear time as per your individual instructions.
- Follow the washing instructions carefully or it can become damaged.

DO NOT

- Do not put on or take off your made to measure product roughly - this can cause damage to the product with ladders or tears or holes in the fabric.
- Do not put on or take off with long finger nails, this can also damage the fabric.

FIT OR SAFETY CONCERNS

Contact your therapist / supplier **IMMEDIATELY** if it is getting really tight, causing red marks or has developed ladders and /or holes.

DMO® products are designed to complement therapy and physical exercise, so should not be removed for exercising unless advised by your therapist, or you have any other concerns that they can help you with.

Wearing time

DO

- Build up wearing time slowly over the first week, as stated below, doubling the amount of time daily until the orthosis is worn throughout the working day.

e.g. 1st day - 1 hour

2nd day - 2 hours

3rd day - 4 hours

4th day - 8 hours

5th day - all day during the day. Thereafter,
wear every day during the day.

DO NOT

- Wear all day immediately. Wear needs to be built up to ensure sensory input, biomechanical changes and fit are monitored.
- do not wear your DMO at night time unless recommended by your doctor or clinician e.g. in the case of EDS patients, where this can be beneficial.

Washing instructions

Follow the care instructions carefully. By taking care of your orthosis you will **prolong its wear and prevent damage**.

DO

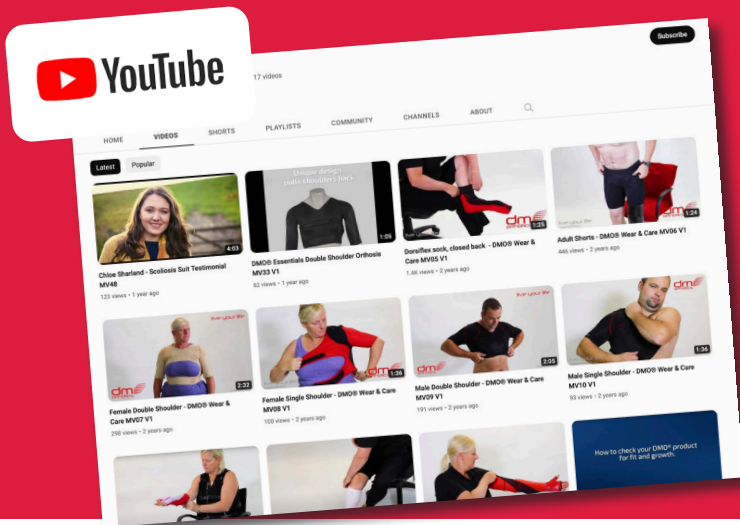
- The orthosis should be washed at least every 2-3 days.
- The orthosis can be hand washed cool or machine washed at 30 degrees.
- Short spin only or roll up in a dry towel to remove excess moisture.
- Allow to completely dry overnight by hanging up indoors.

DO NOT

- DO NOT dry in strong direct sunlight or on a radiator.
- DO NOT WRING OUT– it will stretch out of shape and will cause damage to the materials.
- DO NOT IRON.
- DO NOT USE BLEACH, OR WHITENING AGENTS
- DO NOT USE FABRIC CONDITIONER
- DO NOT DRY CLEAN.
- DO NOT TUMBLE DRY– it will shrink.

For further help and support, we have added how to put on and take off your orthosis to our website please visit: www.dmorthotics.com/productcare.

Regular and correct care of the orthosis will prevent it from developing odour and keep the material supple. If your orthosis is silver treated, this will need to be re-applied after 100 washes as the silver ions start to disperse after 50 washes.



Wearing our products

We have created a range of video guides to help our customers to get the best out of their product. These guides include helpful tips and tricks to wearing our products and how you can best care for them when putting on or taking off.

To view them visit: www.dmorthotics.com/productcare

DMO® products should be worn next to the skin. It is important to build up wear time slowly over the first week, doubling the amount of time daily until worn throughout the day. e.g.

CONTRAINDICATIONS AND PRECAUTIONS/CONSIDERATIONS

Contraindications

There are no known contraindications for using a DMO®. The assessment for a DMO® Custom made product should be undertaken by an authorised medical professional with the correct professional qualifications.

Precautions/Considerations

The following is a list of possible precautions to consider before going ahead with the prescription of a DMO® Custom made product. This should be discussed with your professionally qualified medical professional who may suggest an alternative DMO® product or altering the preferred DMO® product.

Poor temperature regulatory control

A DMO will have no affect on the temperature regulatory centre of the body. However, DMO should be treated as a layer of clothing and clothing layers will need to be adjusted for hot or cold climates accordingly. Adjustments to the prescription can be made such as short legs and arms to help improve heat control.

Primary circulation disorders

Certain primary respiratory problems where muscles are growing weaker due to deterioration of the nerves/muscles, will need careful consideration and may require discussion with the patients medical practitioner - although the suit specification may be changed to accommodate this. Secondary circulation problems associated with Cerebral Palsy can be improved due to improved posture of the trunk/body and improved position of the ribs.

Skin conditions

Skin conditions that might be exacerbated by close contact with synthetic materials for prolonged periods may require further consultation with a healthcare professional who is overseeing the patient's dermatological treatment but this is rarely a contraindication.

Skeletal fragility/brittle bones

Some conditions can be well supported by a DMO® product but this should be discussed with your medical practitioner. Alterations can be made to the preferred product such as the addition of zips or poppers or the use of short arms or legs instead of long arms or legs.

Gastrostomy, stoma and other medical requirements

We can manufacture the custom made product with a special aperture for a gastrostomy peg, stoma, suprapubic catheter etc. This will be added at the fitting stage to ensure precise placement. Please discuss this with your medical practitioner who can seek further advice from the experienced clinical team at DMO®.

DMO® Vest & Leotard

Intended Purpose

The intended purpose of the DM Orthotics DM04/05 Vests and DM06/07 Leotards is to provide trunk, shoulder, upper limb and if leotard is chosen pelvic girdle stabilisation and realignment.

Indications

Children or adults who present with low or high muscle tone which require stabilisation of the effected joints and also realignment of the joints/trunk. This realignment can help with function and prevent contractures. The vests and leotards can help reduce pain and help manage fatigue.

Considerations

Certain cardiovascular circulatory disorders may be contra-indicated and further consultation with the patient's cardiologist may be required.

Intended Patient Population

Adults or children who present with low or high muscle tone who require assistance with posture and alignment of their trunk, shoulder, upper limbs or depending on length of vest or leotard their pelvic girdle.

A carer may be required to assist with donning and doffing the vest or leotard, depending on the functional capabilities of the wearer.

Intended Users

The vest and leotard will require prescription and specification by a competent healthcare professional, typically a qualified orthotist, physiotherapist or occupational therapist, who has received appropriate training in the prescription and use of dynamic

movement orthoses. Such a competent healthcare professional will also be required to assess the fit of the suit and to provide further specification advice to improve the fit of the suit where required.

The wearer of the vest and leotard will typically be a lay person.

The wearer's carer who may be involved in the donning and doffing of the suit, the washing of the suit and the reporting of any issues with the suit will typically be layperson.

The device in question is made to measure and requires specification by a healthcare professional trained in the use of Dynamic Movement Orthoses® (DMO®). This will require a set of measurements which the healthcare professional will have been trained in taking measurements by DM Orthotics. A range of different reinforcement panels must also be prescribed as appropriate by the trained healthcare professional.



Effective for:

- Cerebral Palsy
- Stroke
- Multiple Sclerosis
- Cerebellar Ataxia
- Ehlers-Danlos Syndromes
- & more

Provides:

- Shoulder retraction
- Improved shoulder complex position
- Improved posture
- Improved distal function
- Trunk support
- Reinforcement panelling for strength and stability

Additional features:

- Available with long or short arm
- Various zip fastening options
- Compression fabric for comfort and movement
- Worn under clothing



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DMO® Vest application instructions

How to apply the DMO® Vest.

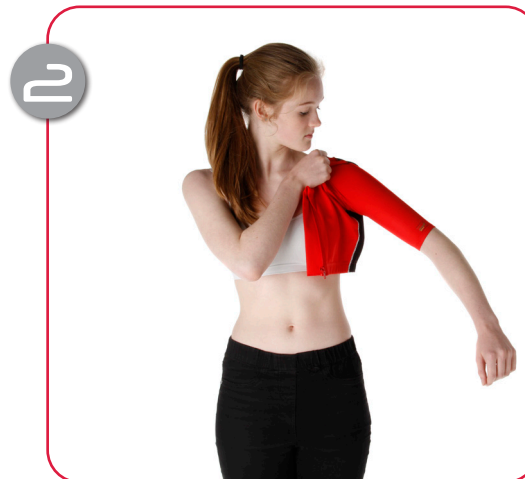
Patient will need to sit down to ensure balance and safety and that the vest is on correctly.

Precautions:

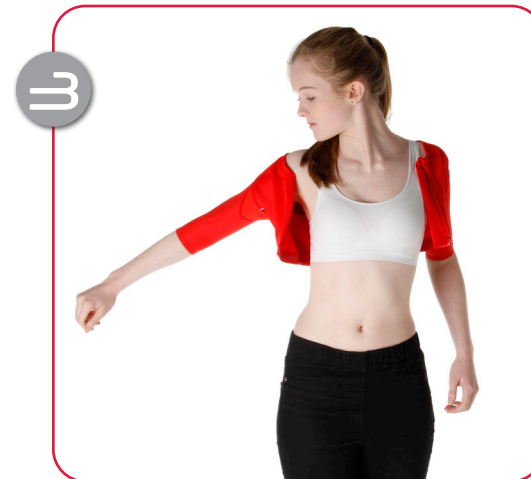
- Ensure the zip liners are in place over the skin prior to pulling up zips and not rolled back.
- The vest should be removed if the patient is sick or has a temperature.
- If there are any concerns with fit i.e. extremities turning blue or feeling overly cold to the touch, then please remove and inform your clinical team immediately for further assessment.



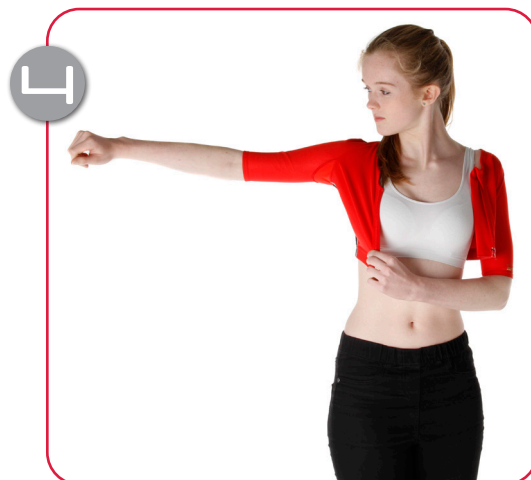
Place one arm into the sleeve.



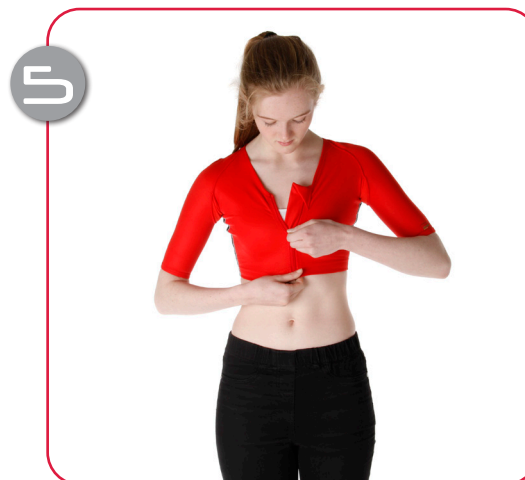
Pull well up to the shoulder.



Take orthosis behind back and feed other arm into the other sleeve.



Pull front panel round.



Fasten front zip taking care to protect the skin from entrapment.



How the vest looks when worn correctly. Please note, your vest may be longer than the one in the picture.

How to remove the DMO® Vest.

Patient will need to sit down to ensure balance and safety.

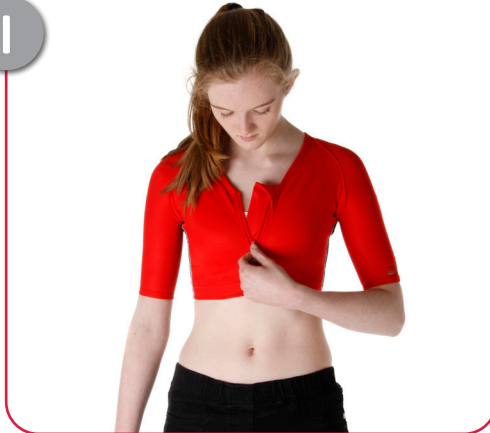
How the Vest should look when on:



Use the QR code above to access our wear and care videos or go to:

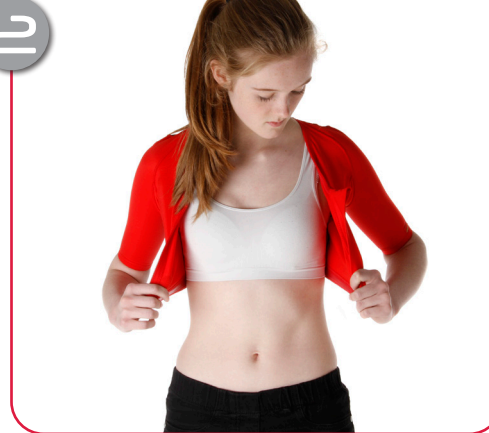
www.dmorthotics.com/productcare

1



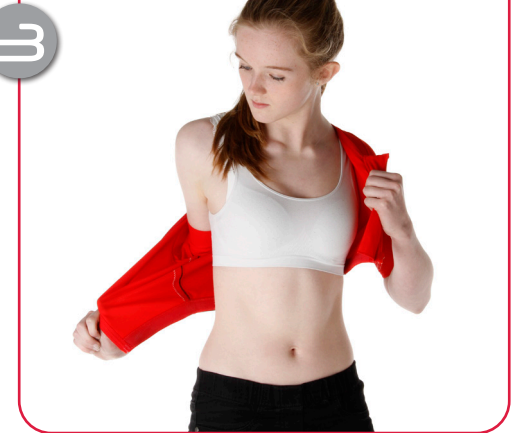
Undo the front zip taking care to protect the skin from entrapment.

2



Open vest at front.

3



Remove one arm from orthosis.

4



Remove the other arm and slide orthosis off over the hand.

To check the fit:

- The orthosis should be a tight fit, but you should be able to fit your index finger under the bottom of the sleeves and legs of the orthosis, as well as around the neck line.
- The stitching/ends of the orthosis may leave slight indentations in the skin, when removed, but if any marks are overly red after 20-30 minutes of its removal, then it may be too tight.
- If in any doubt, as to its appropriate fit, then please notify your therapist immediately, as the orthosis will only be altered free of charge in accordance with our warranty.

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DMO® Leotard application instructions

How to apply the DMO® Leotard.

Patient will need to sit or lie down to ensure balance and safety and that the leotard is on correctly.

Precautions:

- Ensure the zip liners are in place over the skin prior to pulling up zips and not rolled back.
- The leotard should be removed if the patient is sick or has a temperature.
- If there are any concerns with fit i.e. extremities turning blue or feeling overly cold to the touch, then please remove and inform your clinical team immediately for further assessment.



Remove from packaging and undo front and back zip and poppers on groin strap between the legs.



Slip the feet into the opening of the leotard and pull gently up to the knees.



Continue to gently pull body of the leotard up over the hips.



Bring the body of the leotard up to the chest.



For the leotard with sleeves, place the hand/arm into the sleeve section and gently pull over the shoulder.



Repeat with the other sleeve.

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DMO® Leotard application instructions

How to apply the DMO® Leotard.

Patient will need to sit or lie down to ensure balance and safety.

Precautions:

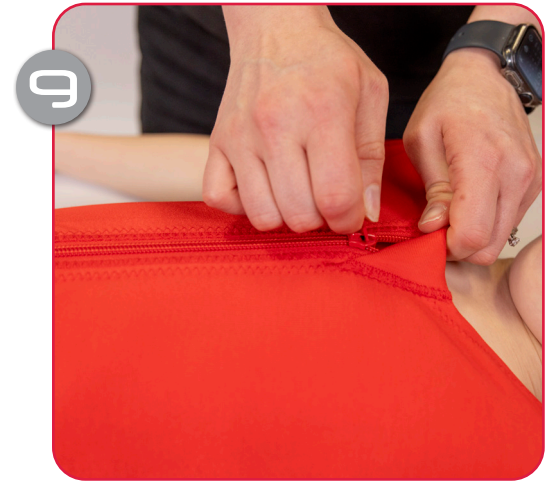
- Ensure the zip liners are in place over the skin prior to pulling up zips and not rolled back.
- The leotard should be removed if the patient is sick or has a temperature.
- If there are any concerns with fit i.e. extremities turning blue or feeling overly cold to the touch, then please remove and inform your clinical team immediately for further assessment.



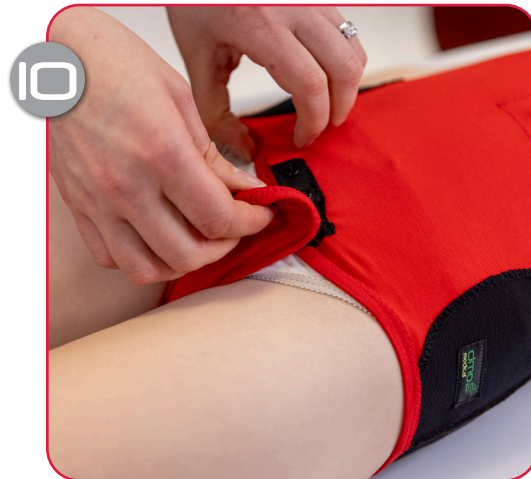
For the leotard without sleeve, place the hand/arm into the arm section and gently pull over the shoulder.



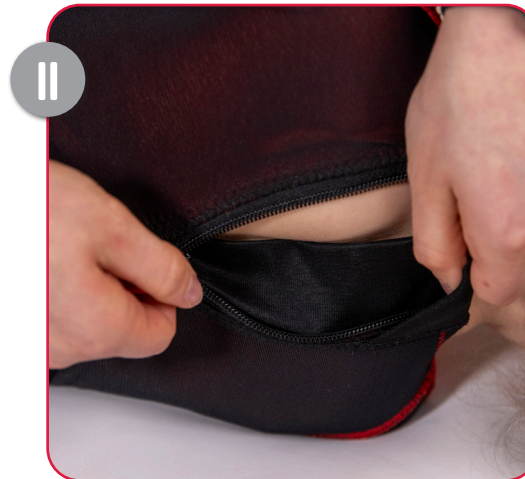
Repeat with the other arm.



Fasten the front zip first.



Fasten the groin strap.

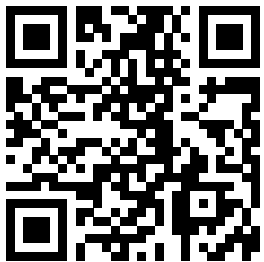


Turn child on to their side and fasten back zip last.

How to remove the DMO® Leotard.

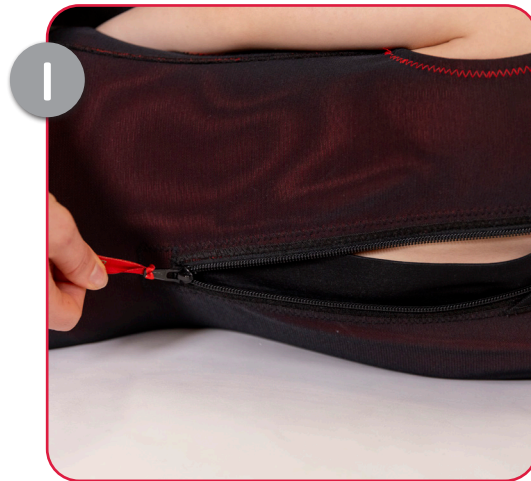
Patient will need to sit or lie down to ensure balance and safety while removing the leotard.

How the Leotard suit should look when on:



Use the QR code above to access our wear and care videos or go to:

www.dmorthotics.com/productcare



Loosen back zip first



Undo the groin strap.



Loosen front zip.



Remove one arm from the sleeve/shoulder of the leotard.

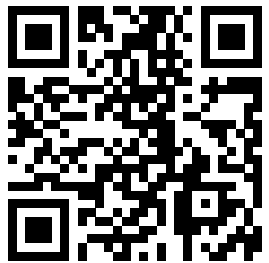


Remove the other arm from the sleeve/shoulder of the leotard.

To check the fit:

- The orthosis should be a tight fit, but you should be able to fit your index finger under the bottom of the sleeves and legs of the orthosis, as well as around the neck line.
- The stitching/ends of the orthosis may leave slight indentations in the skin, when removed, but if any marks are overly red after 20-30 minutes of its removal, then it may be too tight.
- If in any doubt, as to its appropriate fit, then please notify your therapist immediately, as the orthosis will only be altered free of charge in accordance with our warranty.

How the Leotard suit should look when on:



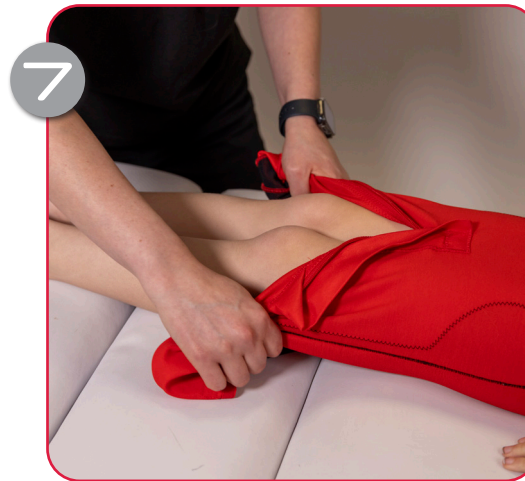
Use the QR code above to access our wear and care videos or go to:
www.dmorthotics.com/productcare

How to remove the DMO® Leotard.

Patient will need to sit or lie down to ensure balance and safety while removing the leotard.



Gently pull leotard down the body towards the hips inside out.



Continue to gently pull down inside out over the legs.



Pull off over the feet.

Disposal of Device Statement

The devices manufactured by DM Orthotics are class 1 / custom made orthotic devices. There are no precautions required to be taken to dispose of DMO® devices. The materials used for manufacture can be disposed of in line with your local arrangements for clothing / materials disposal. We do ask that you please wash the device before disposal.

Serious Incident Statement

If any serious incident occurs in relation to your DMO® device, you should report it immediately to the manufacturer (DM Orthotics) and the competent authority responsible for medical devices in your Member State for example in the UK this would be the Medicines and Healthcare products Regulatory Agency MHRA.

Manufacturer



Patient identification



Product/model ID



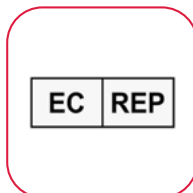
Manufactured in Britain



Distributor



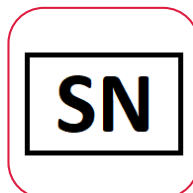
MedEnvoy Global BV
Pr. Margrietplantsoen 33
Suite 123
2595 AM Den Haag
Netherlands



Clinician name



Order number



Medical Device



Please note user modification is not recommended and by altering the orthosis yourself your warranty can be affected or deemed void. Please contact your clinical specialist or DM Orthotics for information on alterations and product modifications.



Manufacturer:
DM Orthotics Ltd
Unit 2 Cardrew Way
Cardrew Industrial Estate
Redruth
Cornwall, UK
TR15 1SS

+44 (0) 1209 219205
www.dmorthotics.com
admin@dmorthotics.com



Designed and constructed in the UK

DM04 - 5054522000036 (UDI-DI)
DM05 - 5054522000043 (UDI-DI)
DM06 - 5054522000050 (UDI-DI)
DM07 - 5054522000067 (UDI-DI)



Manufacturer: DM Orthotics Ltd
Unit 2 Cardrew Way
Cardrew Industrial Estate
Redruth, Cornwall, UK
TR15 1SS

EC

REP

MedEnvoy Global BV
Pr. Margrietplantsoen 33
Suite 123
2595 AM Den Haag
Netherlands