



## **MDR COMPLIANCE CHECKLIST**

FOR EU DISTRIBUTORS

The European Medical Device Regulation (**MDR**) is a new set of regulations that governs the production and distribution of medical devices in Europe, and compliance with the regulation is mandatory for medical device companies that want to sell their products in the European marketplace.

The following document provides distributors in Europe selling products manufactured by WinnCare in the UK, evidence of compliance.



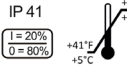

WinnCare is registered as Mangar International Limited and is located at Presteigne, Powys, Wales, UK. LD8 2UF.





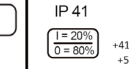

## CE Markings

CE Markings can be found on the rating label on compressors and the product labels.

### Mangar Airflo 24 Rating Label

|  |  |
|--|--|
| <b>WIN CARE</b><br><b>MANGAR AIRFLO 24 COMPRESSOR</b>  |  |
| <br>MANGAR INTERNATIONAL LTD.<br>Presteigne, Powys, LD8 2UF, Wales, UK<br>+44(0)1544 267674 enquiries@winnicare.uk<br>www.winnicare.uk<br><br><br><b>MADE IN CHINA</b> | <b>INPUT:</b> ---<br>Battery charger<br>1 x 30V, 0.45A<br>Optional AC/DC adaptor<br>1 x 20V, 0.45A<br><br><b>OUTPUT:</b> Pmax 0.35 Bar (5psi)<br><br><b>IP 41</b><br><br>I = 20%<br>O = 80% |
| SN: <br>CD0100-24-00100   |  |




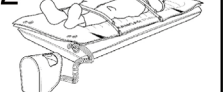


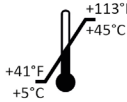
### Mangar Airflo 12 Rating Label

|  |  |
|--|--|
| <b>WIN CARE</b><br><b>MANGAR AIRFLO 12 COMPRESSOR</b>  |  |
| <br>MANGAR INTERNATIONAL LTD.<br>Presteigne, Powys, LD8 2UF, Wales, UK<br>+44(0)1544 267674 enquiries@winnicare.uk<br>www.winnicare.uk<br><br><br><b>MADE IN CHINA</b> | <b>INPUT:</b> ---<br>Battery charger<br>1 x 15V, 0.35A<br>Optional AC/DC adaptor<br>1 x 12V, 11.5A<br><br><b>OUTPUT:</b> Pmax 0.35 Bar (5psi)<br><br><b>IP 41</b><br><br>I = 20%<br>O = 80% |
| SN: <br>CD0100-12-00100   |  |



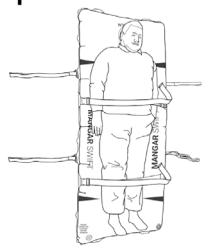
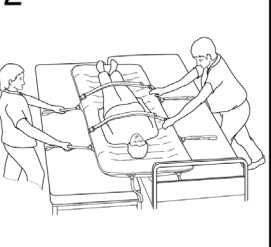
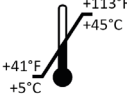
### Mangar Airflo Duo Rating Label

|   |   |
|---|---|
| <b>WIN CARE</b><br><b>MANGAR AIRFLO DUO COMPRESSOR</b>  |   |
| MANGAR INTERNATIONAL LTD.<br>Presteigne, Powys, LD8 2UF, Wales, UK<br>+44(0)1544 267674 enquiries@winnicare.uk www.winnicare.uk<br><br><br><b>MADE IN THE UK</b> |   |
| <b>INPUT:</b> ---<br>Battery charger<br>1 x 30V, 0.45A<br>Optional AC/DC adaptor<br>1 x 24V, 6.65A  | <b>OUTPUT:</b> Pmax 0.086 Bar (1.2psi)<br><br><b>IP 41</b><br><br>I = 20%<br>O = 80% |
| SN: <br>CE1000-01000   |   |


### Mangar Airflo Duo with Rhino lifting cushion

|  |  |  |
|--|--|--|
| <br>MANGAR INTERNATIONAL LTD.<br>Presteigne, Powys, LD8 2UF, Wales, UK<br>Tel: +44(0)1544 267674 www.winnicare.uk<br>enquiries@winnicare.uk<br><br><br><b>MADE IN THE UK</b> | 1 <br>2 <br>3 <br>4  | <b>WIN CARE</b><br><b>MANGAR RHINO LIFTING CUSHION</b><br><br>SN: <input type="text"/><br><br>Max user weight:<br>1100lbs (500kg)<br>Max pressure:<br>2psi (0.14 Bar)<br><br> |
|--|--|--|


### Mangar Airflo Duo with Swift transfer slide

|  |  |   |
|--|--|---|
| <br>MANGAR INTERNATIONAL LTD.<br>Presteigne, Powys, LD8 2UF, Wales, UK<br>Tel: +44(0)1544 267674 www.winnicare.uk<br>enquiries@winnicare.uk<br><br><br><b>MADE IN THE UK</b> | 1 <br>2  | <b>WIN CARE</b><br><b>MANGAR SWIFT TRANSFER SLIDE</b><br><br>SN: <input type="text"/><br><br>Max user weight:<br>1100lbs (500kg)<br>Max pressure:<br>2psi (0.14 Bar)<br><br> |
|--|--|---|


## Mangar Airflo 24 with Elk lifting cushion





**MANGAR INTERNATIONAL LTD.**  
 Presteigne, Powys, LD8 2UF, Wales, UK  
 +44(0)1544 267674 www.winnicare.uk  
 enquiries@winnicare.uk



MADE IN THE UK

1 


2 

3 

**WIN CARE**  
**MANGAR ELK**  
 LIFTING CUSHION


SN

Max user weight:  
 454kg (70 stone)  
 Max pressure:  
 5psi (0.35 Bar)




+122°F  
 +50°C  
 +5°F  
 -15°C

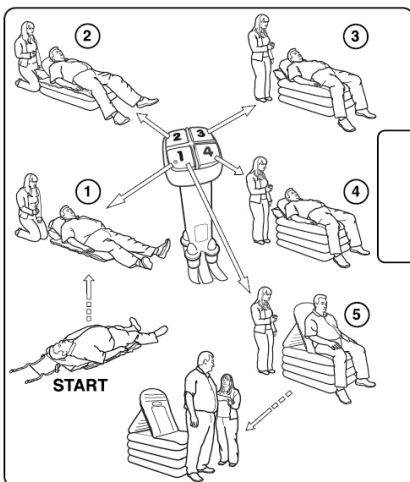
## Mangar Airflo 24 with Eagle Lifting cushion



Max user weight:  
 220kg (35 stone)  
 Max pressure:  
 5psi (0.35 Bar)



+122°F  
 +50°C  
 +5°F  
 -15°C




**WIN CARE**  
**MANGAR EAGLE LIFTING CUSHION**

**MANGAR INTERNATIONAL LTD.**  
 Presteigne, Powys, LD8 2UF, Wales, UK  
 +44(0)1544 267674 www.winnicare.uk  
 enquiries@winnicare.uk




MADE IN THE UK

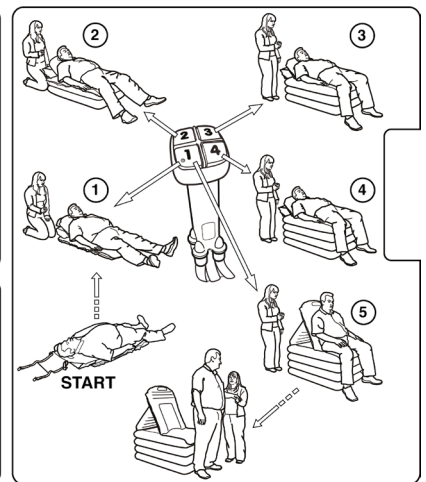
## Mangar Airflo 24 with Camel lifting cushion



Max user weight:  
 320kg (50 stone)  
 Max pressure:  
 5psi (0.35 Bar)



+122°F  
 +50°C  
 +5°F  
 -15°C



**WIN CARE**  
**MANGAR CAMEL LIFTING CUSHION**

**MANGAR INTERNATIONAL LTD.**  
 Presteigne, Powys, LD8 2UF, Wales, UK  
 +44(0)1544 267674 www.winnicare.uk  
 enquiries@winnicare.uk



MADE IN THE UK

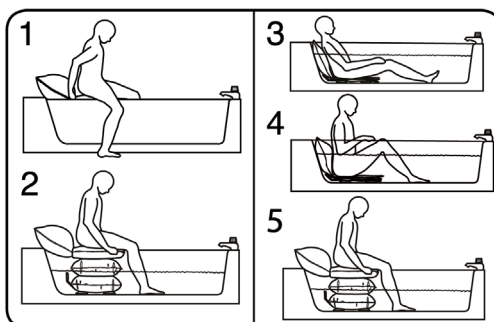
## Mangar Airflo 12 with Bathing cushion



**MANGAR INTERNATIONAL LTD.**  
 Presteigne, Powys, LD8 2UF, Wales, UK  
 +44(0)1544 267674 www.winnicare.uk  
 enquiries@winnicare.uk




MADE IN THE UK



**WIN CARE**  
**MANGAR BATHING CUSHION**

SN


Max user weight:  
 150kg (24 stone)  
 Max pressure:  
 5psi (0.35 Bar)



+122°F  
 +50°C  
 +5°F  
 -15°C

## EU declaration of conformity (certificate)

The declaration on conformity certificate (see example below), identifies the regulations and standards products comply with. Examples of these can be found in user instructions for each product.



### Declaration of Conformity

Mangar International as manufacturer hereby declares that the following products conform to the:

- Applicable provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
- UK Medical Devices Regulations 2002


and following standards:


BS EN 60601-1-6:2010 and A1:2015.      BS EN 60601-1:2006 and A12:2014.  
BS EN 60601-1-11:2015.                      BS EN 62366-1:2015.  
BS EN ISO 10535:2006 (Clause 10).

|                         |  |
|-------------------------|--|
| Trade name:             | Airflo 12 with Bathing Cushion                                 |
| Basic UDI-DI:           | 5020833MPCA030500NY  |
| Product Classification: | ISO 9999:2016, 12 36 18 Assistive products for lifting persons |
| Classification:         | MDR Class 1  |

|                                       |  |
|---------------------------------------|--|
| 21.09.2020<br>_____<br>Place and Date | <br>_____<br>Simon Claridge, CEO |
|---------------------------------------|--|





## **Authorised representative**

WinnCare is the trade name of Mangar International. Mangar International Ltd is wholly owned by WinnCare Group and the French subsidiary, WinnCare France is Mangar International's authorised representative in Europe.

The address is; WinnCare France, 4, Le Pas du Chateau – 85670, Saint-Paul-Mont-Penit, France. Tel: +33 (0)2 51 98 55 64 [www.winnCare.fr](http://www.winnCare.fr)

SRN: FR-AR-000007194

All cartons and Instructions are labelled with the EC REP.



**WINNCARE France**  
**4, Le Pas du Château - 85670**  
**Saint-Paul-Mont-Penit - France**  
**Tél : +33 (0)2 51 98 55 64**  
**[www.winnCare.fr](http://www.winnCare.fr)**

## **Product instructions for use**

All user instructions contain relevant certification and regulation information. These can be found and downloaded on [www.mangarhealth.com](http://www.mangarhealth.com) website.



## UDI-DI

We have established Device Identifiers using the GSI issuing entity.

Device identifiers are as follows:

| <b>SKU</b> | <b>Device Identifiers</b> |
|------------|---------------------------|
| MPCA030518 | 5020833003202             |
| MPCA060400 | 5020833003226             |
| MPCA060421 | 5020833003608             |
| MPCA070400 | 5020833003233             |
| MPCA070421 | 5020833003561             |
| MPCA030500 | 5020833003172             |
| MPCA030518 | 5020833003202             |
| MPCA030530 | 5020833003745             |
| MPCA210400 | 5020833003752             |
| MPCA210431 | 5020833003769             |
| MPCA221332 | 5020833003813             |
| MPCA231332 | 5020833003820             |

Basic UDI-DI's are detailed on the declaration of conformity certificate.

## Post market surveillance

As part of the new MDR regulations, each product has had a clinical evaluation report written by Dr Rachell Russell an occupational therapist specialist. The reports review relevant research materials around each medical device, test reports and feedback from customers from the last 3 years.

Market feedback will be reviewed annually and reflected in future CER reports. Distributors wishing to contribute to CER reports should email [enquiries@winnicare.uk](mailto:enquiries@winnicare.uk) with the subject header of **CER Feedback**.





## **LISTE DE CONTRÔLE DE CONFORMITÉ AU MDR**

POUR LES DISTRIBUTEURS DE L'UE

Le règlement européen sur les dispositifs médicaux (**MDR**) est un nouvel ensemble de réglementations qui régit la production et la distribution des dispositifs médicaux en Europe. La conformité à ce règlement est obligatoire pour les sociétés de dispositifs médicaux qui veulent vendre leurs produits sur le marché européen.

Le document suivant fournit aux distributeurs en Europe qui vendent des produits fabriqués par Winncare au Royaume-Uni, la preuve de leur conformité.



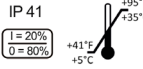

Winncare est enregistré sous le nom de Mangar International Limited et est situé à Presteigne, Powys, Pays de Galles, UK. LD8 2UF.





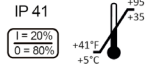

## Marquage CE

Le marquage CE se trouve sur la plaque signalétique des compresseurs et sur les étiquettes des produits.

### Étiquette d'évaluation de l'Airflo 24

|  |  |
|--|--|
| <b>WIN CARE</b><br><b>MANGAR AIRFLO 24 COMPRESSOR</b>  |  |
| <br><small>MANGAR INTERNATIONAL LTD.<br/>                 Presteigne, Powys, LD8 2UF, Wales, UK<br/>                 +44(0)1544 267674 enquiries@winnicare.uk<br/>                 www.winnicare.uk</small> | <b>INPUT:</b> ---<br>Battery charger<br>1 x 30V, 0.45A<br>Optional AC/DC adaptor<br>1 x 20V, 0.45A<br><b>OUTPUT:</b> Pmax 0.35 Bar (5psi)                |
| <br><b>MADE IN CHINA</b>  | <b>IP 41</b><br><br>+95°F / +35°C<br>+41°F / +5°C<br>I = 20%<br>O = 80% |
| SN: <br>CD0100-24-00100   |  |



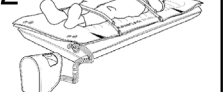



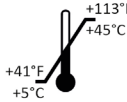
### Étiquette d'évaluation Airflo 12

|  |   |
|--|---|
| <b>WIN CARE</b><br><b>MANGAR AIRFLO 12 COMPRESSOR</b>  |   |
| <br><small>MANGAR INTERNATIONAL LTD.<br/>                 Presteigne, Powys, LD8 2UF, Wales, UK<br/>                 +44(0)1544 267674 enquiries@winnicare.uk<br/>                 www.winnicare.uk</small> | <b>INPUT:</b> ---<br>Battery charger<br>1 x 15V, 0.35A<br>Optional AC/DC adaptor<br>1 x 12V, 11.5A<br><b>OUTPUT:</b> Pmax 0.35 Bar (5psi)                 |
| <br><b>MADE IN CHINA</b>  | <b>IP 41</b><br><br>+95°F / +35°C<br>+41°F / +5°C<br>I = 20%<br>O = 80% |
| SN: <br>CD0100-12-00100  |   |


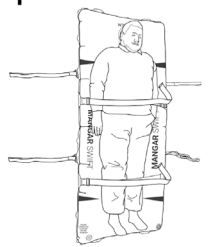
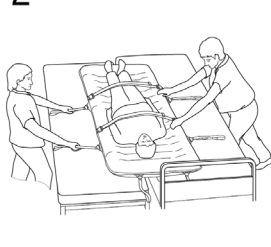

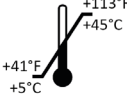
### Étiquette d'évaluation Airflo Duo

|   |  |
|---|--|
| <b>WIN CARE</b><br><b>MANGAR AIRFLO DUO COMPRESSOR</b>  |  |
| <small>MANGAR INTERNATIONAL LTD.<br/>                 Presteigne, Powys, LD8 2UF, Wales, UK<br/>                 +44(0)1544 267674 enquiries@winnicare.uk www.winnicare.uk</small>  |  |
| <br><small>MANGAR INTERNATIONAL LTD.<br/>                 Presteigne, Powys, LD8 2UF, Wales, UK<br/>                 +44(0)1544 267674 enquiries@winnicare.uk www.winnicare.uk</small> | <b>INPUT:</b> ---<br>Battery charger<br>1 x 30V, 0.45A<br>Optional AC/DC adaptor<br>1 x 24V, 6.65A<br><b>OUTPUT:</b> Pmax 0.086 Bar (1.2psi)               |
| <br><b>MADE IN THE UK</b>  | <b>IP 41</b><br><br>+95°F / +35°C<br>+41°F / +5°C<br>I = 20%<br>O = 80% |
| SN: <br>CE1000-01000   |  |

### Mangar Airflo Duo avec coussin de levage Rhino


|   |  |   |
|---|--|---|
| <br><small>MANGAR INTERNATIONAL LTD.<br/>                 Presteigne, Powys, LD8 2UF, Wales, UK<br/>                 Tel: +44(0)1544 267674 www.winnicare.uk<br/>                 enquiries@winnicare.uk</small> | <b>1</b><br><br><b>2</b><br> | <b>WIN CARE</b><br><b>MANGAR RHINO LIFTING CUSHION</b>  |
| <br><b>MADE IN THE UK</b>  | <b>3</b><br><br><b>4</b><br> | SN: <input type="text"/><br>Max user weight:<br>1100lbs (500kg)<br>Max pressure:<br>2psi (0.14 Bar)                     |
|   |  | <br>+113°F / +45°C<br>+41°F / +5°C |

### Mangar Airflo Duo avec L'alaise de transfert Swift


|   |  |   |
|---|--|---|
| <br><small>MANGAR INTERNATIONAL LTD.<br/>                 Presteigne, Powys, LD8 2UF, Wales, UK<br/>                 Tel: +44(0)1544 267674 www.winnicare.uk<br/>                 enquiries@winnicare.uk</small> | <b>1</b><br><br><b>2</b><br> | <b>WIN CARE</b><br><b>MANGAR SWIFT TRANSFER SLIDE</b>   |
| <br><b>MADE IN THE UK</b>  | SN: <input type="text"/><br>Max user weight:<br>1100lbs (500kg)<br>Max pressure:<br>2psi (0.14 Bar)  |   |
|   |  | <br>+113°F / +45°C<br>+41°F / +5°C |



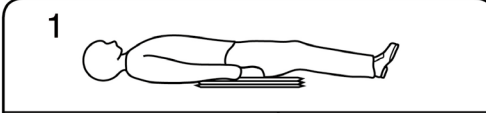


## Mangar Airflo 24 avec coussin de levage Elk



**MANGAR INTERNATIONAL LTD.**  
 Presteigne, Powys, LD8 2UF, Wales, UK  
 +44(0)1544 267674 www.winnicare.uk  
 enquiries@winnicare.uk




MADE IN THE UK

**WIN CARE**  
**MANGAR ELK**  
 LIFTING CUSHION


SN

Max user weight:  
454kg (70 stone)  
 Max pressure:  
5psi (0.35 Bar)




+122°F  
+50°C  
 +5°F  
-15°C

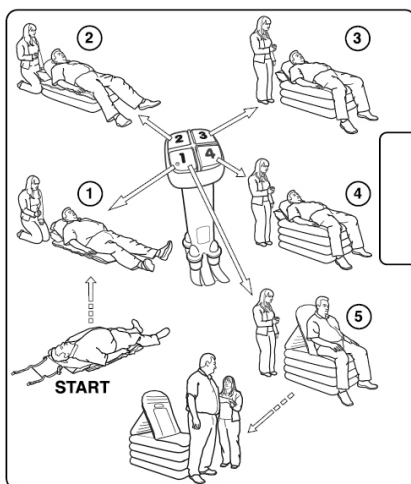
## Mangar Airflo 24 avec coussin de levage Eagle



Max user weight:  
220kg (35 stone)  
 Max pressure:  
5psi (0.35 Bar)



+122°F  
+50°C  
 +5°F  
-15°C



**WIN CARE**  
**MANGAR EAGLE LIFTING CUSHION**

**MANGAR INTERNATIONAL LTD.**  
 Presteigne, Powys, LD8 2UF, Wales, UK  
 +44(0)1544 267674 www.winnicare.uk  
 enquiries@winnicare.uk



MADE IN THE UK

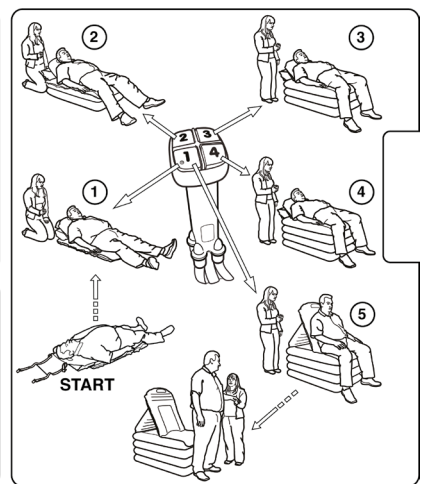
## Mangar Airflo 24 avec coussin de levage Camel



Max user weight:  
320kg (50 stone)  
 Max pressure:  
5psi (0.35 Bar)



+122°F  
+50°C  
 +5°F  
-15°C



**WIN CARE**  
**MANGAR CAMEL LIFTING CUSHION**

**MANGAR INTERNATIONAL LTD.**  
 Presteigne, Powys, LD8 2UF, Wales, UK  
 +44(0)1544 267674 www.winnicare.uk  
 enquiries@winnicare.uk



MADE IN THE UK

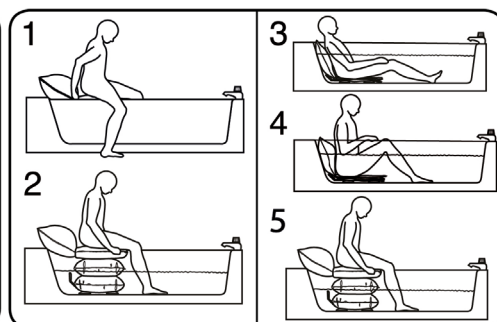
## Mangar Airflo 12 avec coussin de bain



**MANGAR INTERNATIONAL LTD.**  
 Presteigne, Powys, LD8 2UF, Wales, UK  
 +44(0)1544 267674 www.winnicare.uk  
 enquiries@winnicare.uk




MADE IN THE UK



**WIN CARE**  
**MANGAR BATHING CUSHION**

SN

Max user weight:  
150kg (24 stone)  
 Max pressure:  
5psi (0.35 Bar)



+122°F  
+50°C  
 +5°F  
-15°C

## Déclaration de conformité de l'UE (certificat)

Le certificat de déclaration de conformité (voir exemple ci-dessous), identifie les réglementations et les normes auxquelles les produits sont conformes. Vous en trouverez des exemples dans les instructions d'utilisation de chaque produit.



### Declaration of Conformity

Mangar International as manufacturer hereby declares that the following products conform to the:


- Applicable provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
- UK Medical Devices Regulations 2002


and following standards:

BS EN 60601-1-6:2010 and A1:2015.      BS EN 60601-1:2006 and A12:2014.  
BS EN 60601-1-11:2015.                      BS EN 62366-1:2015.  
BS EN ISO 10535:2006 (Clause 10).

Trade name:                      Airflo 12 with Bathing Cushion  
Basic UDI-DI:                      5020833MPCA030500NY  
Product Classification:      ISO 9999:2016, 12 36 18 Assistive products for lifting persons  
Classification:                      MDR Class 1

21.09.2020  
\_\_\_\_\_  
Place and Date

  
\_\_\_\_\_  
Simon Claridge, CEO





## Représentant autorisé

Mangar International est détenu à 100% par WinnCare Group et la filiale française, WinnCare France, est le représentant autorisé de Mangar International en Europe.

Son adresse est la suivante : WinnCare France, 4, Le Pas du Château- 85670, Saint-Paul-Mont-Penit, France. Tél : +33 (0)2 51 98 55 64 [www.winnCare.fr](http://www.winnCare.fr)

SRN: FR-AR-000007194

Tous les cartons et les instructions sont étiquetés avec le REP de la CE.



**WINNCARE France**  
**4, Le Pas du Château - 85670**  
**Saint-Paul-Mont-Penit - France**  
**Tél : +33 (0)2 51 98 55 64**  
**[www.winnCare.fr](http://www.winnCare.fr)**

## Mode d'emploi du produit

Toutes les instructions d'utilisation contiennent des informations pertinentes sur la certification et la réglementation. Vous pouvez les trouver et les télécharger sur le site [www.mangarhealth.com](http://www.mangarhealth.com).

## UDI-DI

Nous avons établi des identifiants de dispositifs en utilisant l'entité émettrice GSI.

Les identifiants des dispositifs sont les suivants:

| <b>SKU</b> | <b>Identificateurs de dispositifs</b> |
|------------|---------------------------------------|
| MPCA030518 | 5020833003202                         |
| MPCA060400 | 5020833003226                         |
| MPCA060421 | 5020833003608                         |
| MPCA070400 | 5020833003233                         |
| MPCA070421 | 5020833003561                         |
| MPCA030500 | 5020833003172                         |
| MPCA030518 | 5020833003202                         |
| MPCA030530 | 5020833003745                         |
| MPCA210400 | 5020833003752                         |
| MPCA210431 | 5020833003769                         |
| MPCA221332 | 5020833003813                         |
| MPCA231332 | 5020833003820                         |

Les UDI-DI de base sont détaillés sur le certificat de déclaration de conformité.

## Surveillance post-marché

Dans le cadre de la nouvelle réglementation MDR, chaque produit a fait l'objet d'un rapport d'évaluation clinique rédigé par le Dr Rachell Russell, ergothérapeute spécialisé. Les rapports passent en revue les documents de recherche pertinents concernant chaque dispositif médical, les rapports d'essai et les réactions des clients au cours des trois dernières années.

Les réactions du marché seront examinées chaque année et reflétées dans les futurs rapports CER. Les distributeurs qui souhaitent contribuer aux rapports du CER doivent envoyer un courriel à [enquiries@winncare.uk](mailto:enquiries@winncare.uk) en indiquant comme objet "**CER Feedback**".

## CHECKLISTE ZUR MDR-EINHALTUNG

FÜR EU-DISTRIBUTOREN

Die Europäische Medizinprodukteverordnung (**MDR**) ist ein neues Regelwerk, das die Produktion und den Vertrieb von Medizinprodukten in Europa regelt. Die Einhaltung der Verordnung ist für Medizinprodukteunternehmen, die ihre Produkte auf dem europäischen Markt verkaufen möchten, zwingend erforderlich.






Das folgende Dokument liefert Händlern in Europa, die von WinnCare in Großbritannien hergestellte Produkte verkaufen, einen Nachweis der Konformität.

WinnCare ist als Mangar International Limited registriert und hat seinen Sitz in Presteigne, Powys, Wales, UK. LD8 2UF.






## CE-Kennzeichnungen

Die CE-Kennzeichnung befindet sich auf dem Typenschild der Kompressoren und auf den Produktetiketten.

### Airflo 24 Typenschild

|  |   |
|--|---|
| <b>WIN CARE</b><br><b>MANGAR AIRFLO 24 COMPRESSOR</b>  |   |
| <br>MANGAR INTERNATIONAL LTD.<br>Presteigne, Powys, LD8 2UF, Wales, UK<br>+44(0)1544 267674 enquiries@winnicare.uk<br>www.winnicare.uk<br><br><b>MADE IN CHINA</b> | <b>INPUT:</b> ---<br>Battery charger<br>1 x 30V, 0.45A<br>Optional AC/DC adaptor<br>1 x 20V, 0.45A<br><b>OUTPUT:</b> Pmax 0.35 Bar (5psi)<br>IP 41<br> +95°F / +35°C<br> +41°F / +5°C<br>I = 20%<br>O = 80% |
| SN: <br>CD0100-24-00100   |   |




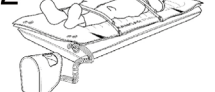




### Airflo 12 Typenschild

|  |   |
|--|---|
| <b>WIN CARE</b><br><b>MANGAR AIRFLO 12 COMPRESSOR</b>  |   |
| <br>MANGAR INTERNATIONAL LTD.<br>Presteigne, Powys, LD8 2UF, Wales, UK<br>+44(0)1544 267674 enquiries@winnicare.uk<br>www.winnicare.uk<br><br><b>MADE IN CHINA</b> | <b>INPUT:</b> ---<br>Battery charger<br>1 x 15V, 0.35A<br>Optional AC/DC adaptor<br>1 x 12V, 11.5A<br><b>OUTPUT:</b> Pmax 0.35 Bar (5psi)<br>IP 41<br> +95°F / +35°C<br> +41°F / +5°C<br>I = 20%<br>O = 80% |
| SN: <br>CD0100-12-00100  |   |



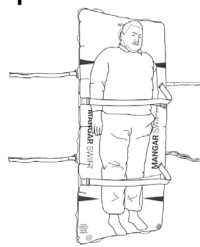
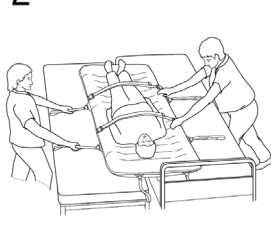


### Airflo Duo Typenschild

|   |  |
|---|--|
| <b>WIN CARE</b><br><b>MANGAR AIRFLO DUO COMPRESSOR</b><br>MANGAR INTERNATIONAL LTD.<br>Presteigne, Powys, LD8 2UF, Wales, UK<br>+44(0)1544 267674 enquiries@winnicare.uk www.winnicare.uk<br><br><b>MADE IN THE UK</b> |  |
| <b>INPUT:</b> ---<br>Battery charger<br>1 x 30V, 0.45A<br>Optional AC/DC adaptor<br>1 x 24V, 6.65A  | <b>OUTPUT:</b> Pmax 0.086 Bar (1.2psi)<br>IP 41<br> +95°F / +35°C<br> +41°F / +5°C<br>I = 20%<br>O = 80% |
| SN: <br>CE1000-01000   |  |


### Mangar Airflo Duo mit Rhino-Hebekissen

|  |  |   |
|--|--|---|
| <br>MANGAR INTERNATIONAL LTD.<br>Presteigne, Powys, LD8 2UF, Wales, UK<br>Tel: +44(0)1544 267674 www.winnicare.uk<br>enquiries@winnicare.uk<br><br><b>MADE IN THE UK</b> | 1 <br>2 <br>3 <br>4  | <b>WIN CARE</b><br><b>MANGAR RHINO LIFTING CUSHION</b><br>SN: <input type="text"/><br>Max user weight:<br>1100lbs (500kg)<br>Max pressure:<br>2psi (0.14 Bar)<br> +113°F / +45°C<br> +41°F / +5°C |
|--|--|---|

### Mangar Airflo Duo mit Transferschlitten Swift

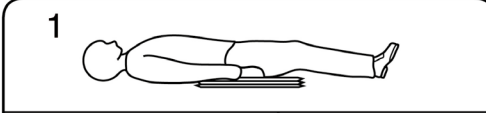


|  |  |  |
|--|--|--|
| <br>MANGAR INTERNATIONAL LTD.<br>Presteigne, Powys, LD8 2UF, Wales, UK<br>Tel: +44(0)1544 267674 www.winnicare.uk<br>enquiries@winnicare.uk<br><br><b>MADE IN THE UK</b> | 1 <br>2  | <b>WIN CARE</b><br><b>MANGAR SWIFT TRANSFER SLIDE</b><br>SN: <input type="text"/><br>Max user weight:<br>1100lbs (500kg)<br>Max pressure:<br>2psi (0.14 Bar)<br> +113°F / +45°C<br> +41°F / +5°C |
|--|--|--|

## Mangar Airflo 24 mit Elk-Hebekissen



**MANGAR INTERNATIONAL LTD.**  
 Presteigne, Powys, LD8 2UF, Wales, UK  
 +44(0)1544 267674 www.winnicare.uk  
 enquiries@winnicare.uk

**UK CA CE**  
 MADE IN THE UK


**WIN CARE**  
**MANGAR ELK**  
 LIFTING CUSHION

SN

Max user weight:  
 454kg (70 stone)  
 Max pressure:  
 5psi (0.35 Bar)

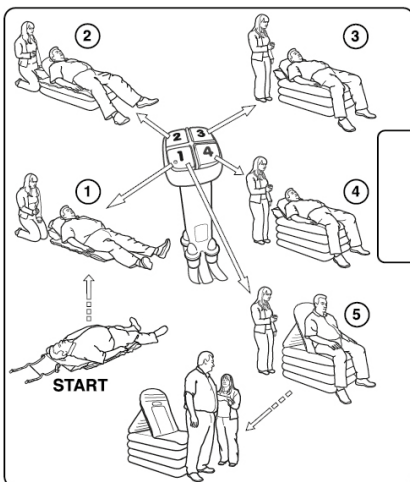
+122°F  
 +50°C  
 +5°F  
 -15°C

## Mangar Airflo 24 mit Eagle-Hebekissen



Max user weight:  
 220kg (35 stone)  
 Max pressure:  
 5psi (0.35 Bar)

+122°F  
 +50°C  
 +5°F  
 -15°C




**WIN CARE**  
**MANGAR EAGLE** LIFTING CUSHION

**MANGAR INTERNATIONAL LTD.**  
 Presteigne, Powys, LD8 2UF, Wales, UK  
 +44(0)1544 267674 www.winnicare.uk  
 enquiries@winnicare.uk

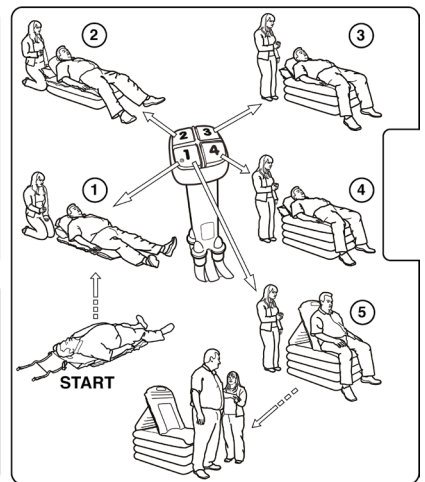
**UK CA CE**  
 MADE IN THE UK

## Mangar Airflo 24 mit Camel-Hebekissen



Max user weight:  
 320kg (50 stone)  
 Max pressure:  
 5psi (0.35 Bar)

+122°F  
 +50°C  
 +5°F  
 -15°C



**WIN CARE**  
**MANGAR CAMEL** LIFTING CUSHION

**MANGAR INTERNATIONAL LTD.**  
 Presteigne, Powys, LD8 2UF, Wales, UK  
 +44(0)1544 267674 www.winnicare.uk  
 enquiries@winnicare.uk

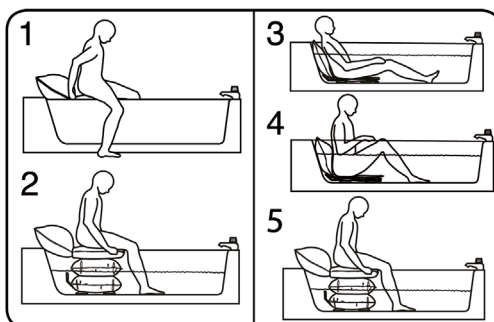
**UK CA CE**  
 MADE IN THE UK

## Mangar Airflo 12 mit Badekissen



**MANGAR INTERNATIONAL LTD.**  
 Presteigne, Powys, LD8 2UF, Wales, UK  
 +44(0)1544 267674 www.winnicare.uk  
 enquiries@winnicare.uk

**UK CA CE**  
 MADE IN THE UK



**WIN CARE**  
**MANGAR BATHING** CUSHION


SN

Max user weight:  
 150kg (24 stone)  
 Max pressure:  
 5psi (0.35 Bar)

+122°F  
 +50°C  
 +5°F  
 -15°C

## EU-Konformitätserklärung (Zertifikat)

Die Bescheinigung über die Konformitätserklärung (siehe Beispiel unten), gibt an, welchen Vorschriften und Normen die Produkte entsprechen. Beispiele dafür finden Sie in den Gebrauchsanweisungen der einzelnen Produkte.



### Declaration of Conformity

Mangar International as manufacturer hereby declares that the following products conform to the:

- Applicable provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
- UK Medical Devices Regulations 2002


and following standards:


BS EN 60601-1-6:2010 and A1:2015.      BS EN 60601-1:2006 and A12:2014.  
BS EN 60601-1-11:2015.                      BS EN 62366-1:2015.  
BS EN ISO 10535:2006 (Clause 10).

|                         |  |
|-------------------------|--|
| Trade name:             | Airflo 12 with Bathing Cushion                                 |
| Basic UDI-DI:           | 5020833MPCA030500NY  |
| Product Classification: | ISO 9999:2016, 12 36 18 Assistive products for lifting persons |
| Classification:         | MDR Class 1  |

|                                       |  |
|---------------------------------------|--|
| 21.09.2020<br>_____<br>Place and Date | <br>_____<br>Simon Claridge, CEO |
|---------------------------------------|--|





## Bevollmächtigter

Mangar International ist zu 100 % im Besitz der WinnCare Gruppe und die französische Tochtergesellschaft, WinnCare France, ist der autorisierte Vertreter von Mangar International in Europa.

Die Adresse lautet; WinnCare France, 4, Le Pas du Château- 85670, Saint-Paul-Mont-Penit, Frankreich. Tel: +33 (0)2 51 98 55 64 [www.winnCare.fr](http://www.winnCare.fr)

SRN: FR-AR-000007194

Alle Kartons und Anleitungen sind mit dem EC REP gekennzeichnet.



**WINNCARE France**  
**4, Le Pas du Château - 85670**  
**Saint-Paul-Mont-Penit - France**  
**Tél : +33 (0)2 51 98 55 64**  
**[www.winnCare.fr](http://www.winnCare.fr)**

## Gebrauchsanweisung für das Produkt

Alle Gebrauchsanweisungen enthalten relevante Zertifizierungs- und Vorschrifteninformationen. Diese können auf der Website [www.mangarhealth.com](http://www.mangarhealth.com) gefunden und heruntergeladen werden.

## UDI-DI

Wir haben Gerätekennungen über die GSI-Ausgabestelle festgelegt.

Die Gerätekennungen sind wie folgt:

| SKU        | Gerätebezeichner |
|------------|------------------|
| MPCA030518 | 5020833003202    |
| MPCA060400 | 5020833003226    |
| MPCA060421 | 5020833003608    |
| MPCA070400 | 5020833003233    |
| MPCA070421 | 5020833003561    |
| MPCA030500 | 5020833003172    |
| MPCA030518 | 5020833003202    |
| MPCA030530 | 5020833003745    |
| MPCA210400 | 5020833003752    |
| MPCA210431 | 5020833003769    |
| MPCA221332 | 5020833003813    |
| MPCA231332 | 5020833003820    |

Die grundlegenden UDI-DI's sind auf dem Konformitätserklärungszertifikat aufgeführt.

## Überwachung nach dem Markt

Im Rahmen der neuen MDR-Vorschriften wurde für jedes Produkt ein klinischer Bewertungsbericht von Dr. Rachell Russell, einer Fachärztin für Ergotherapie, verfasst. In den Berichten werden relevante Forschungsmaterialien rund um jedes Medizinprodukt, Testberichte und Rückmeldungen von Kunden aus den letzten 3 Jahren überprüft.

Das Marktfeedback wird jährlich überprüft und in zukünftigen CER-Berichten berücksichtigt. Händler, die einen Beitrag zu den CER-Berichten leisten möchten, sollten eine E-Mail an [enquiries@winnicare.uk](mailto:enquiries@winnicare.uk) mit dem Betreff "**CER-Feedback**" senden.