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www.ehob.com

European Directive #93/42/EEC

Adverse Incident Center

Department of Health Room 1201

Hannibal House-Elephant and Castle UK

London, England

SEI 6TQ

#### **DECLARATION OF CONFORMITY**

#### **Medical Devices**

We hereby declare that the distributed CE marked products, specified on the attached product listing, conform to products covered in accordance with Annex II of the "EC-Directive", the Council Directive 93/94/EEC of 14<sup>th</sup> of June 1993, concerning medical devices.

We declare that the distributed CE marked products comply within Class I requirements and meet the provisions of the EC-Directive applicable.

This declaration is based on the application and maintenance of the approved quality for the design, manufacture and final inspection of the products concerned, in accordance with Annex VII of the CE directive.

This declaration of conformity covers WAFFLEIPI Brand Products, EHOB DermaCare • Foam Mattress Prism\* Products and WAFFLE• FootHofdIEI Products as specified in the product listings (attachments A, B, C, D, E, and F) and is valid for all products concerned bearing the CE marking and manufactured at EHOB, Inc.; 205 N. Belmont Ave.; Indianapolis, IN 46222 U.S.A.

Authorized Reg resentative:

Dated: 1.J't 1-

em es Bui - V.P. of Commercial Operation, EHOB, Inc.

Attachment 'A' WAFFLEIEI Products

Attachment 'B' • DermaCare 11 Foam Mattress Prism

Attachment 'C'- FootHoldIPI Products

Attachment 'D'• TruVuerM Products

Attachment 'E'- Safe Patient Handling Products

Attachment 'F' Continuous Inflation Devices

Attachment 'G'- Product Accessories



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Attachment 'A'

#### International Business

## EHOB, Inc.'s Product Listing

## Complying with CE Marking European Directive #93/42/EE

### **WAFFLES Products**

Product Codes	Descriptions
1056ECXX	Extended Care Mattress
1006ECXX	Extended Care Plus Mattress
1006ECPX	Extended Care Plus Mattress With Pump
1004ECXX	Expansion Control Mattress
1025ECPX	Econo-Care Plus Mattress With Pump
1100RXX	Operating Room-Full Size
200WCXX	Waffle Cushion 41X41 Centimeters
214PCXX	Waffle Pediatric Pad
218WCXX	Waffle Cushion 48X48 Centimeters
240WCXX	Waffle Bariatric Wheelchair Cushion
201 WPXX	Waffle Multi-Care Pad
207GDCX	Geriatric Day Chair Pad
303FWXX	Foot Waffle Small
304FWXX	Foot Waffle Medium
30SFWXX	Foot Waffle Large
345CXXX	Foot Waffle Cradle
4000AXXX	Mattress Overlay 193X86X8 Centimeters
4010AXXX	Bariatric/Double Overlay 193X119X8 Centimeters
4020AXXX	Mattress Trolley/Theatre Overlay 198XS9XS
	Centimeters
4230AXXX	Seat Cushion 43X43X4 Centimeters
4240AXXX	Seat Cushion 51XS1XS Centimeters
4250AXXX	Bariatric Seat Cushion 71X56XS Centimeters
4260AXXX	Multi-Care Pad 91X38XS Centimeters
4270AXXX	Riser/Recliner Pad 183X53X8 Centimeters
4400AXXX	Heel Elevator Custom Petite
4410AXXX	Heel Elevator Custom Standard
4420AXXX	Heel Elevator Custom Extra
4430AXXX	Heel Elevator One Size
4440AXXX	Heel Elevator Original One Size
546ORXX	Asure Surgery Table Pad Straps 12/Bag
540MADX	M.A.D Hand Pump for Inflation
4280A	Short Riser/Recliner Pad 99X56X6 Centimeters
4290A	Long Riser/Recliner Pad 175X56X8 Centimeters
PPATRPWDG	Position Perfect Wedge w/Cover



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ATTACHMENT 'B'

#### **International Business**

## **EHOB. Inc's Product listing**

## Complying with CE Marking European Directive #93/42/EEC

#### **DermaCare® Products**

Product Codes	Descriptions
30-9315	Prism Mattress Replacement Reflex Plus Foam- Size: 89X191X15 Centimeters
30-9316	Prism Mattress Replacement Reflex Plus Foam- Size: 89X203X15
30-9317	Prism Mattress Replacement Reflex Plus Foam- Size: 89X213X15
30-9318	Prism Mattress Replacement Reflex Plus Foam- Size: 81X203X15



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### ATTACHMENT 'C'

### **International Business**

# **EHOB, Inc.'s Product listing**

# Complying with CE Marking European Directive #93/42/EEC

### FootHold® Products

Product Codes	Descriptions
FHI0-SMEX-A	Waffle FootHold With Splint, Secure Stick Sole
	and Anti-Rotation Bar-Small
FHIO-SMWS	Waffle FootHold With Splint- Small
FHI0-MDEX-A	Waffle FootHold With Splint, Secure Stick Sole
	and Anti-Rotation Bar-Medium
FHIO-MDWS	Waffle FootHold With Splint- Medium
FHI0-LGEX-A	Waffle FootHold With Splint, Secure Stick Sole
	and Anti-Rotation Bar-Large
FHI0-LGWS	Waffle FootHold With Splint-Large
FHIO-XLEX-A	Waffle FootHold With Splint, Secure Stick Sole
	and Anti-Rotation Bar-Extra Large
FHI0-XLWS	Waffle FootHold With Splint- Extra Large
FHI0-XPEX-A	Waffle FootHOld With Splint, Secure Stick Sole
	and Anti-Rotation Bar- Extra Plus
FHIO-XPWS	Waffle FootHold With Splint- Extra Plus
FHIO-SMSS	Waffle FootHold With Secure Stick Sole-Small
FHI0-MDSS	Waffle FootHold with Secure Stick Sole Medium
FHI0-LGSS	Waffle FootHold With Secure Stick Sole- Large
FHI0-XLSS	Waffle FootHold With Secure Stick Sole Extra
	Large
FHI0-SMXX	Waffle FootHold - Small
FHI0-MDXX	Waffle FootHold -Medium
FHI0-LGXX	Waffle FootHold- Large
FHI0-ELXX	Waffle FootHold- Extra Large
FH20-SMXX	Waffle FootHold Plus- Small
FH20-MDXX	Waffle FootHold Plus- Medium
FH20-LGXX	Waffle FootHold Plus- Large
FH20-XLXX	Waffle FootHold Plus- Extra Large



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## ATTACHMENT 'D'

#### **International Business**

## EHOB, Inc.'s Product Listing

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### TruVue™ Products

Product Codes	Description
TRUVUEPW010	Petite Heel Protector With Wedge
TRUVUESWOI0	Standard Heel Protector With Wedge
TRUVUEXW010	Extra Large Heel Protector With Wedge
TRUVUEPT0I0	Petite Heel Protector
TRUVUESDOI0	Standard Heel Protector
TRUVUEXL0I0	Extra Large Heel Protector



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#### ATTACHMENT 'E'

### **International Business**

## EHOB, Inc.'s Product Listing

## Complying with CE Marking European Directive #93/42/EEC

## Safe Patient Handling Products

Product Codes	Description
PPERG0XX0IO	Ergo Straps and Mesh Bag
PPSGSHTX020	Safe Glide
PPSGULTR0I0	Safe Glide Ultra
PPATRXXX010	ATR



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## ATTACHMENT 'F'

#### **International Business**

## EHOB, Inc.'s Product Listing

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## **Continuous Inflation Devices**

Product Codes	Description
CPIIO0US0I0	CAir Pump
CL1200US010	CAir Lite Pump



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## ATTACHMENT 'G'

### **International Business**

## EHOB, Inc.'s Product Listing

## Complying with CE Marking European Directive #93/42/EEC

### **Product Accessories**

Product Codes	Description
520LAOX	LAD Hand Pump
200WCOV	Cushion Cover for 4203
218COVX	Cushion Cover for 4240
240WCOV	Cushion Cover for 4250
201WPCOV	M ulti -Care Pad Cover for 4260
207GOCOV	Day Chair Pad Cover for 4270
IOOOWAFMCB	Mattress Carrying Bag
IOOOWAFCCB	Cushion and Heel Elevator Carrying Bag
5460RXX	Assure Surgery Table Str aps- 12/Bag
1025PPWC010	Position Perfect Wedge With Cover
TRUVUEWSOIO	Petite and Standard Wedge
TRUVUEWLOIO	Extra Large Wedge