

DECLARATION OF CONFORMITY

1) **Manufacturer** (Name, department): **The Hygenic Corporation**

Address: **1245 Home Avenue, Akron, OH 44310, United States**

and

2) **European authorized representative:** **CEpartner4U BV,**

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;**

(on product labels printed as:

CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.eu)

3) **Product(s)** (name, type or model/batch number, etc.):

Thera-Band Products

see appendix

4) **The product(s) described above is in conformity with:**

<u>Title</u>	<u>Document No.</u>
Medical Device Directive	93/42/EEC

5) **Additional information** (conformity procedure, Notified Body, CE certificate, Registration nr., etc.):

Conformity assessment procedure for CE marking: Medical Device Directive, Annex VII

Akron, OH, USA; 2015-03-12



Marco Ayaya, Director Corporate Compliance, Hygenic

(Place & date of issue (yyyy-mm-dd))

(name; function and signature of manufacturer)

Appendix

Date: 2015-03-12

List of devices:

Device name	Type/ model/ref number	Risk class / rule ¹	First date of CE-compliance
Thera-Band Resistance Bands Latex			
Thera-Band Resistance Bands – Latex (all sizes, all colors)	Bands	Class I / rule 1	2009-10-05
Thera-Band Resistance Bands – Latex Band Loop (all sizes, all colors)	Bands	Class I / rule 1	2009-10-05
Thera-Band Resistance Band – Latex Dispenser (all sizes, all colors)	Bands	Class I / rule 1	2009-10-05
Thera-Band Resistance Band – Latex Packs (all sizes, all colors)	Bands	Class I / rule 1	2009-10-05
Thera-Band Resistance Bands – Latex Zipper Bag (all sizes, all colors)	Bands	Class I / rule 1	2009-12-17
Thera-Band Resistance Bands Latex Free			
Thera-Band Resistance Bands - Latex Free (all sizes, all colors)	Bands	Class I / rule 1	2009-11-25
Thera-Band Resistance Bands – Latex Free Dispenser (all sizes, all colors)	Bands	Class I / rule 1	2012-06-13
Thera-Band Resistance Bands Latex Free TPE (all sizes, all colors)	Bands	Class I / rule 1	2013-06-13
Thera-Band Resistance Bands Latex Free Active Recovery Packs (beginner, advanced)	Bands	Class I / rule 1	2013-06-13
TheraBand CLX Consecutive Loops (all sizes, all colors)	Bands	Class I / rule 1	2015-03-12
Thera-Band Tubing Latex			
Thera-Band Tubing Latex (all sizes, all colors)	Tubing	Class I / rule 1	2009-10-05
Thera-Band Accessories			

¹ See risk classification in Medical Device Directive, annex IX

Device name	Type/ model/ref number	Risk class / rule ¹	First date of CE-compliance
Thera-Band Assist Strap (with D ring, without D ring)	Accessories	Class I / rule 1	2009-11-25
Thera-Band Exercise Handles (with D ring, without D ring)	Accessories	Class I / rule 1	2009-11-25
Thera-Band Sports Handle	Accessories	Class I / rule 1	2009-11-25
Thera-Band Door Anchor	Accessories	Class I / rule 1	2009-11-25
Thera-Band Extremity Strap (with D ring, without D ring)	Accessories	Class I / rule 1	2009-11-25
Thera-Band Accessories Kit	Accessories	Class I / rule 1	2009-11-25
Thera-Band Bar w/D Ring Connector	Accessories	Class I / rule 1	2012-11-20
Thera-Band Hand Trainer			
Thera-Band Progressive Hand Trainer – Latex (all colors)	Hand Trainer	Class I / rule 1	2009-10-05
Thera-Band Hand X Trainer (Cross Trainer) (all colors)	Hand Trainer	Class I / rule 1	2012-06-13
Thera-Band Hand Exerciser (all colors)	Hand Trainer	Class I / rule 1	2013-06-26
Thera-Band Stretch Strap			
Thera-Band Stretch Strap	Stretch Strap	Class I / rule 1	2011-04-24
Thera-Band Foot Roller			
Thera-Band Foot Roller	Foot Roller	Class I / rule 1	2011-04-24
Thera-Band Shoulder Pulley			
Thera-Band Shoulder Pulley	Shoulder Pulley	Class I / rule 1	2011-04-24
Thera-Band Rollers			
Thera-Band Foam Roller (12", 36", 36 1/5")	Foam Roller	Class I / rule 1	2012-06-13
Thera-Band Roller Massagers (standard, portable)	Roller Massager	Class I / rule 1	2012-06-13
Thera-Band Roller Wraps (all colors)	Roller Wraps	Class I / rule 1	2012-06-13
Thera-Band Exercise Station			
Thera-Band Exercise Station (Exercise Station, Wall Station)	Exercise Station	Class I / rule 1	2012-11-20
Thera-Band Exercise Station Tubing Assembly (Exercise Station, Wall Station)	Exercise Station	Class I / rule 1	2012-11-20

Device name	Type/ model/ref number	Risk class / rule ¹	First date of CE-compliance
Thera-Band Stability Products			
Thera-Band Rocker Board	Stability	Class I / rule 1	2012-11-20
Thera-Band Wobble Board	Stability	Class I / rule 1	2012-11-20
Stability Disc	Stability	Class I / rule 1	2012-11-20
Stability Trainer (all colors)	Stability	Class I / rule 1	2012-11-20
Thera-Band Exercise Balls			
Thera-Band Exercise Balls (all sizes, all colors)	Exercise Ball	Class I / rule 1	2012-11-20
Thera-Band PRO Series SCP (all sizes, all colors)	Exercise Ball	Class I / rule 1	2012-11-20
Mini Ball	Exercise Ball	Class I / rule 1	2012-11-20
Thera-Band Weights			
Soft Weights (all colors)	Weights	Class I / rule 1	2012-11-20
Ankle Weights (all colors)	Weights	Class I / rule 1	2012-11-20
Thera-Band Flexbar			
FlexBar (sizes, all colors)	Weights	Class I / rule 1	2013-06-26