

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 <i>see appendix</i>

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; 2019-10-23 

Hanneman, Paul-VP Regulatory Affairs and QA

(Place & date of issue (yyyy-mm-dd)) (name; function and signature of manufacturer)

Appendix

Date: 2019-10-23


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 High Resistance Bands – Latex (all sizes, all colors)	Bands	Class I / rule 1	2019-10-23
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

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
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			
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 / rule1	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

Device name	Type/ model/ref number	Risk class / rule ¹	First date of CE-compliance
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
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
TheraBand Aquatics			
Kickroller Floatation Device with Padded Grip	Aquatics	Class I / rule 1	2016-10-4
Swim Bar with Padded Grip	Aquatics	Class I / rule 1	2016-10-4
Closed Chain Buoyancy Disk	Aquatics	Class I / rule 1	2016-10-4
Hand Bar with Padded Grip Light	Aquatics	Class I / rule 1	2016-10-4
Hand Bar with Padded Grip Medium	Aquatics	Class I / rule 1	2016-10-4

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Device name	Type/ model/ref number	Risk class / rule ¹	First date of CE-compliance
Hand Bar with Padded Grip Heavy	Aquatics	Class I / rule 1	2016-10-4
Webbed Pull Buoy Swim Training Aid 4" x 6"	Aquatics	Class I / rule 1	2016-10-4
Webbed Pull Buoy Swim Training Aid 4" x 7"	Aquatics	Class I / rule 1	2016-10-4
Webbed Pull Buoy Swim Training Aid 4" x 6"	Aquatics	Class I / rule 1	2016-10-4
Tadpole Swim Belt	Aquatics	Class I / rule 1	2016-10-4
Youth Swim Belt	Aquatics	Class I / rule 1	2016-10-4
Young Adult Swim Belt	Aquatics	Class I / rule 1	2016-10-4
Aquafins® Aquatic Exercise Kit	Aquatics	Class I / rule 1	2016-10-4
Thera-Band/ Cramer Tape			
Kinesiology Tape (All Colors)	Tape	Class I / rule 1	2018-02-27