


Balanced Body, Inc.

Subject: CE, Declaration of Conformity (DOC): Reformer-Trapeze Combination (RTC)	Status: Released	Rev: 2	Document #: BB00100	 balanced body™
Author: Kit Spelman	Process Owner: Engineering	Date: 01/12/21	Page: 1 of 2	

CONTROLLED DOCUMENT

Declaration of Conformity


This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
Balanced Body, Inc.	5909 88 th Street Sacramento, CA 95828 USA Tel: +1 916-388-2838 Fax: +1 916-379-9277	TBD

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone/fax/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	Product Code / Catalog Number	Basic UDI-DI
See file Appendix 3.1 for details	See file Appendix 3.1 for details	0810052148000LS
Intended Purpose		
The <i>Reformer-Trapeze Combination</i> device is intended by the manufacturer to be used by people for the purpose of: physiotherapy, rehabilitation, the prevention, treatment and relief of injuries, supportive, functional therapy for a disability, or for general strengthening and improving the mobility of the human body.		

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RISK CLASS FOR MEDICAL DEVICES

Device Classification	Common Specifications
Class <u> 1 </u> Rule <u> 1 </u>	Device is non-invasive, Device is not active, Device is non-sterile, Self-Certified

Balanced Body, Inc. declares that the above-mentioned products meet the provision of the following EU legislation:

- MDR (EU) 2017/745

COMPANY REPRESENTATIVE: Ken Endelman

TITLE: Owner, C.E.O.

SIGNATURE: *Ken Endelman*

PLACE: Balanced Body, Sacramento, CA, USA

DATE: 03/08/2021

Device Labeling Reference

Release Date

01.15.2021

Revision 1

UDI-DI (GTIN)	Product Description	SKU	Assembly Instr	For Use Instr	Qty./Package	Packaging Box	Label #
(01)00810052140001	Ref, Studio, Revo, 14", Strata	11931	17293	15458	1	402-001	11931
(01)00810052140018	Assy, Bottom, Cadillac, Contrology, Custom	17125C	17305	17219	1	17181	17125C
(01)00810052140025	Assy, Bottom, Cadillac, Contrology, Stock	17125	17305	17219	1	17181	17125
(01)00810052140032	Assy, Bottom, Toy Box, Cad, Contrology, Cstm	17127C	17305	17219	1	17181	17127C
(01)00810052140049	Assy, Bottom, Toy Box, Cad, Contrology, Stk	17127	17305	17219	1	17181	17127
(01)00810052140056	Assy, Canopy w PTB Slider, CenterLine	15697	15460	17443	1	404-000	15697
(01)00810052140063	Assy, Canopy w PTB Slider, CenterLine, Custom	15697C	15460	17443	1	404-000	15697C
(01)00810052140070	Assy, Canopy w PTB Slider, RTC	15326	17301	15452	1	404-000	15326
(01)00810052140087	Assy, Canopy w PTB Slider, RTC, Custom	15326C	17301	15452	1	404-000	15326C
(01)00810052140094	Assy, Canopy w PTB Slider, Trap Table	15328	17302	15454	1	404-000	15328
(01)00810052140100	Assy, Canopy w PTB Slider, Trap Table, Custom	15328C	17302	15454	1	404-000	15328C
(01)00810052140117	Assy, Canopy, Cadillac, Contrology	17124	17305	17219	1	17178	17124
(01)00810052140124	Assy, Canopy, Cadillac, Contrology, Cstm	17124C	17305	17219	1	17178	17124C
(01)00810052140131	Assy, Tower w Slider, Centerline, Retrofit	15270	15463	17441	1	box1189	15270
(01)00810052140148	Assy, Tower w Slider, Cntrl, Retrofit, Custom	15270C	15463	17441	1	box1189	15270C
(01)00810052140155	Assy, Tower w Slider, Studio, Retrofit	15268	15457	15458	1	box1189	15268
(01)00810052140162	Assy, Tower w Slider, Studio, Retrofit, Custom	15268C	15457	15458	1	box1189	15268C
(01)00810052140179	Ref, A1b	12315	17291	10896	1	box3001	12315
(01)00810052140186	Ref, A1b, Custom	12315C	17291	10896	1	box3001	12315C
(01)00810052140193	Ref, A1b, Pre-Built	12317	17291	10896	1	box3001	12317
(01)00810052140209	Ref, A1b, Pre-Built, Custom	12317C	17291	10896	1	box3001	12317C
(01)00810052140216	Ref, A1b, Stretch	12322	17291	10896	1	box1128	12322
(01)00810052140223	Ref, A1b, Stretch, Custom	12322C	17291	10896	1	box1128	12322C
(01)00810052140230	Ref, A2, w/o Risers	12307	17292	10828	1	412-000	12307
(01)00810052140247	Ref, A2, w/o Risers, Custom	12307C	17292	10828	1	412-000	12307C
(01)00810052140254	Ref, Clinical, 24", Strata	12244	17285	15451	1	404-009	12244
(01)00810052140261	Ref, Clinical, Custom	12244C	17285	15451	1	404-009	12244C
(01)00810052140278	Ref, Contrology, 86", Pre-built	17171	17304	16526	1	box2017	17171
(01)00810052140285	Ref, Contrology, Custom	16472C	17304	16526	1	box2017	16472C
(01)00810052140292	Ref, Contrology, JGrimes, 80in	16095	17304	16526	1	box2012	16095
(01)00810052140308	Ref, Rialto	16088	17303	16074	1	box2004	16088
(01)00810052140315	Ref, Rialto, Pre-Built	17057	17303	16074	1	box2004	17057
(01)00810052140322	Ref, Studio, CenterLine, 14", Strata	12263	15286	17441	1	402-001	12263
(01)00810052140339	Ref, Studio, CenterLine, Custom	12263C	15286	17441	1	402-001	12263C
(01)00810052140346	Ref, Studio, CenterLine, w Tower, Custom	12267C	15286	17441	1	404-009	12267C
(01)00810052140353	Ref, Studio, Classic, 14", Strata	12168	17293	15458	1	402-001	12168
(01)00810052140360	Ref, Studio, Classic, Custom	12168C	17293	15458	1	402-001	12168C
(01)00810052140377	Ref, Studio, Classic, RTC, Custom	12179C	17301	15452	1, 1	404-009, 404-000	12179, 15326C
(01)00810052140384	Ref, Studio, Classic, w Tower, Custom	12181C	17293	15458	1	404-009	12181C
(01)00810052140391	Ref, Studio, Clinical, w Tower, 24", Strata	12251	17293	15458	1	404-009	12251
(01)00810052140407	Ref, Studio, Clinical, w Tower, Custom	12251C	17293	15458	1	404-009	12251C
(01)00810052140421	Ref, Studio, Infinity, Custom	12000C	17293	15451	1	404-009	12000C
(01)00810052140438	Ref, Studio, Infinity, w Tower, Custom	12008C	17293	15458	1	404-009	12008C
(01)00810052140445	Ref, Studio, Revo XSR, 14", Maple	16737	17293	15458	1	402-001	16737
(01)00810052140469	Ref, Studio, Revo, 18", Maple, Predrill Tower	17288C	17293	15458	1	402-001	17288C
(01)00810052140476	Ref, Studio, Revo, Custom	11931C	17293	15458	1	402-001	11931C
(01)00810052140483	Ref, Studio, Revo, RTC, Custom bottom only	11944C	17301	15452	1	404-009	11944C
(01)00810052140490	Ref, Studio, Revo, RTC, Strata, 24"bottom only	11944	17301	15452	1	404-009	11944
(01)00810052140506	Ref, Studio, Revo, w Tower, Custom	11949C	17293	15458	1	404-009	11949C
(01)00810052140513	Ref, Studio, Revo, w Tower, Strata, 18"	11949	17293	15458	1	404-009	11949
(01)00810052140520	Ref, Studio, XSR, Custom	16737C	17293	15458	1	402-001	16737C
(01)00810052140537	Ref, Studio, XSR, w Tower, Custom	16942C	17293	15458	1	404-009	16942C
(01)00810052140544	Tower w/mats, Rialto, Stock	16487	17303	16074	1	16636	16487
(01)00810052140551	Tower, A1b	11929	17291	10896	1	401-000	11929
(01)00810052140568	Tower, A2	11927	17292	10828	1	412-008	11927
(01)00810052140575	Tower, Pre-Built, A1b	11930	17291	10896	1	401-000	11930
(01)00810052140582	Tower, Rialto	16754	17303	16074	1	16636	16754
(01)00810052140599	Trap Table, Bottom, 24", Maple	12216	17302	15454	1	404-037	12216
(01)00810052140605	Trap Table, Bottom, Centerline, Custom	12236C	15460	17443	1	404-037	12236C
(01)00810052140612	Trap Table, Bottom, Custom	12216C	17302	15454	1	404-037	12216C
(01)00810052140629	Trap Table, wSlider, 24" Maple	15278	17302	15454	1, 1	404-037, 404-000	12216, 15326
(01)00810052140636	Trap Table, Centerline, w PTB, stk top/cust bot	15924C	15460	17443	1, 1	404-037, 404-000	12236C, 15697
(01)00810052140643	Trap Table, w PTB Slider, custom top/stock btm	15925C	17302	15454	1, 1	404-037, 404-000	12216, 15326C
(01)00810052140650	Trap Table, w PTB Slider, custom top/stock btm	15372C	17302	15454	1, 1	404-037, 404-000	12216C, 15326C
(01)00810052140667	Trap Table, w PTB Slider, stock top/custom btm	15366C	17302	15454	1, 1	404-037, 404-000	12216C, 15326
(01)00810052140674	RTC, Revo, w PTB Slider, 24", Strata	15279	17301	15452	1, 1	404-009, 404-000	11944, 15326
(01)00810052140681	RTC, Revo, w PTB Slider, custom top/custom btm	15344C	17301	15452	1, 1	404-009, 404-000	11944C, 15326C
(01)00810052140698	RTC, Classic, w PTB Slider, stock top/custom btm	15339C	17301	15452	1, 1	404-009, 404-000	12179C, 15326
(01)00810052140704	RTC, Revo, w PTB Slider, stock top/custom btm	15336C	17301	15452	1, 1	404-009, 404-000	11944C, 15326
(01)00810052140711	RTC, Revo, w PTB Slider, custom top/stock btm	15740C	17301	15452	1, 1	404-009, 404-000	11944, 15326C
(01)00810052140728	RTC, Classic, w PTB Slider, custom top/custom btm	15350C	17301	15452	1, 1	404-009, 404-000	12179C, 15326C
(01)00810052140735	Cadillac, Contrology, Stock	17037	17305	17219	1, 1	17181, 17178	17124, 17125
(01)00810052140742	Cadillac, Contrology, Cstm Top/Cstm Toy Box Btm	17137C	17305	17219	1, 1	17181, 17178	17127C, 17124C
(01)00810052140759	Cadillac, Contrology, Stk Top/Cstm Toy Box Btm	17136C	17305	17219	1, 1	17181, 17178	17127C, 17124
(01)00810052140766	Cadillac, Contrology, Cstm Top/Stk Toy Box Btm	17134C	17305	17219	1, 1	17181, 17178	17127, 17124C
(01)00810052140773	Cadillac, Contrology, w Toy Box	17123	17305	17219	1, 1	17181, 17178	17127, 17124
(01)00810052140780	Cadillac, Contrology, Stk Top/Cstm Btm	17135C	17305	17219	1, 1	17181, 17178	17125C, 17124

(01)00810052140797	Cadillac, Contrology, Cstm Top/Stk Btm	17133C	17305	17219	1, 1	17181, 17178	17125, 17124C
(01)00810052140803	Cadillac, Contrology, Cstm Top/Cstm Btm	17123C	17305	17219	1, 1	17181, 17178	17125C, 17124C
(01)00810052140810	Ref, A2 w Risers	12505	17292	10828	1	412-000	12307
(01)00810052140827	Ref, A2 w Risers, Custom	12505C	17292	10828	1	412-000	12307C
(01)00810052140834	Ref, A2, 15"	12499	17292	10828	1	412-000	12307
(01)00810052140841	Ref, A2, 15", Custom	12499C	17292	10828	1	412-000	12307C
(01)00810052140858	Complete Top System, A2	12501	17292	10828	1, 1, 1	412-000, 412-008, 15289	12307, 11927, 12313
(01)00810052140865	Complete Top System, A2, Cstm Ref & Mats	12501C	17292	10828	1, 1, 1	412-000, 412-008, 15289	12307C, 11927, 12313C
(01)00810052140872	Complete Top System, A1b	12509	17291	10896	1, 1, 1	box3001, 401-000, 15385	12315, 12304, 11929
(01)00810052140889	Complete Top System, A1b, Custom	12509C	17291	10896	1, 1, 1	box3001, 401-000, 15385	12315C, 12304C, 11929
(01)00810052140896	Ref, A1b, 14"	12511	17291	10896	1	box3001	12315
(01)00810052140902	Ref, A1b, 14", Custom	12511C	17291	10896	1	box3001	12315C
(01)00810052140919	Ref, A1b, 14", Stretch	12513	17291	10896	1	box1128	12322
(01)00810052140926	Ref, A1b, 14", Stretch, Custom	12513C	17291	10896	1	box1128	12322C
(01)00810052140933	Complete Top System, A1b, Stretch	12515	17291	10896	1, 1, 1	box1128, 401-000, 10918	12322, 12952, 11929
(01)00810052140940	Complete Top System, A1b, Stretch, Custom	12515C	17291	10896	1, 1, 1	box1128, 401-000, 10918	12322C, 12952C, 11929
(01)00810052140957	Tower w Mat, w Slider, Studio	15269	17293	15458	1, 1	box1189, 11010	15268, 12042
(01)00810052140964	Tower w Mat, wSlider, Studio, stock tower/cstm mat	15383C	17293	15458	1, 1	box1189, 11010	15268, 12042C
(01)00810052140971	Tower w Mat, wSlider, Studio, cstm tower/stock mat	15384C	17293	15458	1, 1	box1189, 11010	15268C, 12042
(01)00810052140988	Tower w Mat, wSlider, Studio, cstm tower/cstm mat	15382C	17293	15458	1, 1	box1189, 11010	15268C, 12042C
(01)00810052140995	Tower wSlider, SR Stretch, Rtrft w Mat, Cstm Mats	15932C	17293	15458	1, 1	box1189, 11010	15268, 12111C
(01)00810052141008	Tower wSlider, SR Stretch, Rtrft w Mat, Both Cstm	15933C	17293	15458	1, 1	box1189, 11010	15268C, 12111C
(01)00810052141015	Tower w Mat, wSlider, Centerline, stk tower/cstm mat	15379C	15286	17441	1, 1	box1189, 11010	12149C, 15270
(01)00810052141022	Tower w Mat, wSlider, Centerline	15271	15286	17441	1, 1	box1189, 11010	12149, 15270
(01)00810052141039	Tower w Mat, wSlider, Centerline, cstm tower & mat	15381C	15286	17441	1, 1	box1189, 11010	12149C, 15270C
(01)00810052141046	Tower w Mat, wSlider, Centerline, cstm tower/stk mat	15380C	15286	17441	1, 1	box1189, 11010	12149, 15270C
(01)00810052141053	Tower & Mat, A2	12495	17292	10828	1, 1	412-008, 15289	12313, 11927
(01)00810052141060	Tower & Mat, A2, Custom	12495C	17292	10828	1, 1	412-008, 15289	12313C, 11927
(01)00810052141077	Tower & Mat, A1b	12507	17291	10896	1, 1	401-000, 15385	12304, 11929
(01)00810052141084	Tower & Mat, A1b, Custom	12507C	17291	10896	1, 1	401-000, 15385	12304C, 11929
(01)00810052141091	Tower & Mat, A1b, Stretch	12517	17291	10896	1, 1	401-000, 10918	12952, 11929
(01)00810052141107	Tower & Mat, A1b, Stretch, Custom	12517C	17291	10896	1, 1	401-000, 10918	12952C, 11929
(01)00810052141114	Rialto Ref w/tower and mat	16569	17303	16074	1, 1	box2004, 16636	16088, 16487
(01)00810052141145	Reformer, Contrology, 86in, w Tower	17424	17638	17639	1	17705	17424
(01)00810052141152	Reformer, Contrology, w Tower, Custom	17424C	17638	17639	1	17705	17424C