

Declaration of Conformity

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

MANUFACTURER		
Name of Company	Address	SRN
Ortho-Tain, Inc.	Carr 861 KM 5.0 Barrio Pina Toa Alta, PR 00953 USA	PR-MF-000008715

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
Orthodontic Dental Appliances	List attached	List attached
Intended Purpose	Photo	
Accessories to orthodontic devices – PVC & TPE dental appliances to aid in the correction of teeth position and/or to maintain teeth in desired position or maintain jaw relation.	Representative sample 	

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	Common Specifications
Class 1 Rule 5	

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

- Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE: Francheska C. Medina

TITLE: QA Manager, PPRC

SIGNATURE: *Francheska C. Medina*

PLACE: Carr 861 K.M 5.0 Barrio Pinas Toa Alta, PR 00953

DATE: 12/04/2021

Product Code / Catalog Number List

Ortho-Tain Nite-Guide

Item Number	Size	Item Number	Size
10C-1400-E	1 C	40C-1400-E	4 C
15C-1400-E	1 ½ C	45C-1400-E	4 ½ C
20C-1400-E	2 C	50C-1400-E	5 C
25C-1400-E	2 ½ C	55C-1400-E	5 ½ C
30C-1400-E	3 C	60C-1400-E	6 C
35C-1400-E	3 ½ C	<i>UDI-DI – D866C1400E0</i>	

Ortho-Tain Softee Appliance

Item Number	Size	Item Number	Size
10C-4100-C-S	1 CS	40C-4100-C-S	4 CS
15C-4100-C-S	1 ½ CS	45C-4100-C-S	4 ½ CS
20C-4100-C-S	2 CS	50C-4100-C-S	5 CS
25C-4100-C-S	2 ½ CS	55C-4100-C-S	5 ½ CS
30C-4100-C-S	3 CS	60C-4100-C-S	6 CS
35C-4100-C-S	3 ½ CS	<i>UDI-DI – D866C41000</i>	

Soft Ortho-Tain Positioner

Item Number	Size	Item Number	Size
10N-1000	1N	30X-1000	3X
15N-1000	1 ½ N	35X-1000	3 ½ X
20N-1000	2N	40X-1000	4X

25N-1000	2 ½ N	45X-1000	4 ½ X
30N-1000	3 N	50X-1000	5X
35N-1000	3 ½ N	55X-1000	5 ½ X
40N-1000	4 N	60X-1000	6X
45N-1000	4 ½ N	<i>UDI-DI – D866X10000</i>	
50N-1000	5N	20U-1000	2U
55N-1000	5 ½ N	25U-1000	2 ½ U
60N-1000	6N	30U-1000	3U
65N-1000	6 ½ N	35U-1000	3 ½ U
70N-1000	7N	40U-1000	4U
<i>UDI-DI – D866N10000</i>		45U-1000	4 ½ U
10X-1000	1X	50U-1000	5U
15X-1000	1 ½ X	55U-1000	5 ½ U
20X-1000	2X	60U-1000	6U
25X-1000	2 ½ X	<i>UDI-DI – D866U10000</i>	

Medium Ortho-Tain Positioner

Item Number	Size	Item Number	Size
10N-1100	1N	30X-1100	3X
15N-1100	1 ½ N	35X-1100	3 ½ X
20N-1100	2N	40X-1100	4X
25N-1100	2 ½ N	45X-1100	4 ½ X
30N-1100	3 N	50X-1100	5X
35N-1100	3 ½ N	55X-1100	5 ½ X

40N-1100	4 N	60X-1100	6X
45N-1100	4 ½ N	<i>UDI-DI – D866X11000</i>	
50N-1100	5N	20U-1100	2U
55N-1100	5 ½ N	25U-1100	2 ½ U
60N-1100	6N	30U-1100	3U
65N-1100	6 ½ N	35U-1100	3 ½ U
70N-1100	7N	40U-1100	4U
<i>UDI-DI – D866N11000</i>		45U-1100	4 ½ U
10X-1100	1X	50U-1100	5U
15X-1100	1 ½ X	55U-1100	5 ½ U
20X-1100	2X	60U-1100	6U
25X-1100	2 ½ X	<i>UDI-DI – D866U11000</i>	

Ortho-Tain Interim “G” Retainers Clear

Item Number	Size	Item Number	Size
20I-1600-BC	2I	50I-1600-BC	5I
25I-1600-BC	2 ½ I	55I-1600-BC	5 ½ I
30I-1600-BC	3I	60I-1600-BC	6I
35I-1600-BC	3 ½ I	65I-1600-BC	6 ½ I
40I-1600-BC	4I	70I-1600-BC	7I
45I-1600-BC	4 ½ I	<i>UDI-DI – D866I1600CLEAR0</i>	

Ortho-Tain Interim “G” Retainers Blue

Item Number	Size	Item Number	Size
20I-1600-BB	2 I	50I-1600-BB	5I

25I-1600-BB	2 ½ I	55I-1600-BB	5 ½ I
30I-1600-BB	3 I	60I-1600-BB	6I
35I-1600-BB	3 ½ I	65I-1600-BB	6 ½ I
40I-1600-BB	4I	70I-1600-BB	7I
45I-1600-BB	4 ½ I	<i>UDI-DI – D866I1600BLUE0</i>	

Ortho-Tain Interim “G” Retainers Green

Item Number	Size	Item Number	Size
20I-1600-BG	2 I	50I-1600-BG	5I
25I-1600-BG	2 ½ I	55I-1600-BG	5 ½ I
30I-1600-BG	3I	60I-1600-BG	6I
35I-1600-BG	3 ½ I	65I-1600-BG	6 ½ I
40I-1600-BG	4I	70I-1600-BG	7I
45I-1600-BG	4 ½ I	<i>UDI-DI – D866I1600GREEN0</i>	

Ortho-Tain Interim “G” Retainers Magenta

Item Number	Size	Item Number	Size
20I-1600-BM	2I	50I-1600-BM	5I
25I-1600-BM	2 ½ I	55I-1600-BM	5 ½ I
30I-1600-BM	3I	60I-1600-BM	6I
35I-1600-BM	3 ½ I	65I-1600-BM	6 ½ I
40I-1600-BM	4I	70I-1600-BM	7I
45I-1600-BM	4 ½ I	<i>UDI-DI – D866I1600PINK0</i>	

Ortho-Tain Interim “G” Retainers Orange

Item Number	Size	Item Number	Size
20I-1600-BO	2I	50I-1600-BO	5I
25I-1600-BO	2 ½ I	55I-1600-BO	5 ½ I
30I-1600-BO	3I	60I-1600-BO	6I
35I-1600-BO	3 ½ I	65I-1600-BO	6 ½ I
40I-1600-BO	4I	70I-1600-BO	7I
45I-1600-BO	4 ½ I	UDI-DI – D866I1600ORANGE0	

Ortho-Tain Interim “G” Retainers Purple

Item Number	Size	Item Number	Size
20I-1600-BP	2I	50I-1600-BP	5I
25I-1600-BP	2 ½ I	55I-1600-BP	5 ½ I
30I-1600-BP	3I	60I-1600-BP	6I
35I-1600-BP	3 ½ I	65I-1600-BP	6 ½ I
40I-1600-BP	4I	70I-1600-BP	7I
45I-1600-BP	4 ½ I	UDI-DI – D866I1600PURPLE0	

Occlus-o-Guide

Item Number	Size	Item Number	Size
10G-1200	1G	20H-1300	2H
15G-1200	1 ½ G	25H-1300	2 ½ H
20G-1200	2G	30H-1300	3H
25G-1200	2 ½ G	35H-1300	3 ½ H
30G-1200	3G	40H-1300	4H
35G-1200	3 ½ G	45H-1300	4 ½ H

40G-1200	4G	50H-1300	5 H
45G-1200	4 ½ G	55H-1300	5 ½ H
50G-1200	5G	60H-1300	6H
55G-1200	5 ½ G	65H-1300	6 ½ H
60G-1200	6G	70H-1300	7H
65G-1200	6 ½ G	<i>H'S UDI-DI – D866H13000</i>	
70G-1200	7G	<i>G'S UDI-DI – D866G12000</i>	

Ortho-Tain Ortho-T

Item Number	Size	Item Number	Size
10N-4200-NT	1 NT	30X-4200-XT	3 XT
15N-4200-NT	1 ½ NT	35X-4200-XT	3 ½ XT
20N-4200-NT	2 NT	40X-4200-XT	4 XT
25N-4200-NT	2 ½ NT	45X-4200-XT	4 ½ XT
30N-4200-NT	3 NT	50X-4200-XT	5 XT
35N-4200-NT	3 ½ NT	55X-4200-XT	5 ½ XT
40N-4200-NT	4 NT	60X-4200-XT	6 XT
45N-4200-NT	4 ½ NT	<i>UDI-DI – D866X42000</i>	
50N-4200-NT	5 NT	20U-4200-UT	2 UT
55N-4200-NT	5 ½ NT	25U-4200-UT	2 ½ UT
60N-4200-NT	6 NT	30U-4200-UT	3 UT
65N-4200-NT	6 ½ NT	35U-4200-UT	3 ½ UT
70N-4200-NT	7 NT	40U-4200-UT	4 UT
<i>UDI-DI – D866N42000</i>		45U-4200-UT	4 ½ UT
10X-4200-XT	1 XT	50U-4200-UT	5 UT
15X-4200-XT	1 ½ XT	55U-4200-UT	5 ½ UT
20X-4200-XT	2 XT	60U-4200-UT	6 UT
25X-4200-XT	2 ½ XT	<i>UDI-DI – D866U42000</i>	

Ortho-Tain Snore Cure

Item Number	Size
00S-1700	00S
<i>UDI-DI – D866SC0</i>	

Habit-Corrector

Item Number	Size
HCCY40-B	HCY (Youth size)
HCCY40-BP	HCY (Youth size)
HCCY40-BT	HCY (Youth size)
HCCY40-BPT	HCY (Youth size)
HCCA40AN	HCA (Adult size)
HCCA40BP	HCA (Adult size)
HCCP40B	HCP (Pedo size)
HCCP40BP	HCP (Pedo size)
HCCP40BT	HCP (Pedo size)
HCCP40BPT	HCP (Pedo size)
HCCT40AT	HCT (Toddler size)
HCCA50A	HCA (Adult size)
HCCA50AP	HCA (Adult size)
HCCP50A	HCP (Pedo size)
HCCT50A	HCT (Toddler size)
UDI-DI – D866HCC0	

Hawley Form Retainer

Item Number	Size
HFL-2100	HFL R(one size)
HFL-2100-W	HFL E(one size)
HFU-2100	HFU R(one size)

HFU-2100-T-W	HFU E(one size)
HFU-2100-W	HFU A(one size)
<i>UDI-DI – D866HF0</i>	

Class III

Item Number	Size
CLASSIII40A	CIII
YCLASSIII40A	YCIII
CLASSIII50A	CIII
YCLASSIII50A	YCIII
<i>UDI-DI – D866CLASSIII0</i>	