Orthodontic Design and Production, Inc.

California Office

Orthodontic Design and Production, Inc.
1370 Decision Street, Suite D
Vista, California USA 92081
Telephone (760) 734-3995
Facsimile: (760) 734-1735
E-mail: info@odpinc.com

Registration Information

Notified Body: BSI – Notified Body # 0086

Address: Kitemark Court
Davey Avenue, Knowlhill
Milton Keynes, MK5 8PP
United Kingdom

Conformity Assessment

Applicable Council Directive..... 93/42/EEC (as amended by 2007/47/EC)

Classification..... Class 1 per Annex IX, Definition 1.1 and Rule 1

Route to Compliance: Annex VII Per Article 11-5

Authorized Representative

mdi Europa GmbH
Langenhagen Str. 71 30855 Langenhagen
Germany

DECLARATION OF CONFORMITY

CLASS I Devices

Product Identification					
UMDNS Code	Product Family / Product Description	Part Number Prefix (Part Number begins with...)			
13-380	Dental Retractors				
	Cheek Retractors	M986-*	M987-*	M993-*	M995-*
	Photo Cheek Retractors	M996-*	M997-*	M998-*	
	Lip Retractors	M984-*	M985-*		
14-071	Toothbrush				
	Home Care Kit	M340-*			
16-189	Dental Wax				
	Flavor Wax	M200-*	M200K-*		
16-350	Impression Trays				
	Prolock Impression Trays	S310-*	S311-*		
16-366	Mouth Guards				
	Ultra-Guard Mouth Guards	M300-*	M305-*		
	Home Care Kit	M340-*			

(list continues)

Authorized Representative:

M. Sander-Griesemann VPO
Name, Title

M. Sander-Griesemann
Signature

20 March 2014
Date

mdi Europa GmbH
Langenhagener Str. 71 · 30855 Langenhagen
Phone +49-511. 39 08 95 30
Fax +49-511. 39 08 95 39

mdiEuropa
THE MEDICAL DEVICE SERVICE-MANAGEMENT

Product Identification				
UMDNS Code	Product Family / Product Description	Part Number Prefix (Part Number begins with…)		
16-664	Orthodontic Hand Instruments			
	Instruments	ISP-*		
	Pliers and Cutters	IPL1-*	IPL2-*	IPL-*
17-595	Protectors, Teeth			
	Lip Protectors	M410-*		
18-411	Pads			
	Stress Relief Pads	M350-*		

~end of list~

We, Orthodontic Design & Production, Inc. (ODP) of Vista, California, USA, declare with sole responsibility that the products listed above meet the essential requirements of the Council Directive 93/42/EEC (as amended) pertaining to Medical Devices. The products referenced herein are controlled by ODP's quality management system.

Signed this 10th day of March, 2014, by _____

Richard Merrell, Regulatory Affairs Manager

We hereby appoint mdi Europa GmbH, Langenhagener Str. 71, 30855 Langenhagen in Germany to act as European Authorized Representative, as explicitly stated in Article 1, §2(g) of Directive 98/79/EC.

The necessary pre-requisites for placing the CE mark on the above mentioned products, and marketing them in all Member States of the European Union, have thus been fulfilled.

Signed this 20 day of March, 2014;

By: _____

Title: VP Operations

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mdi Europa
THE MEDICAL DEVICE SERVICE-MANAGEMENT