



Orthodontic Design  
and Production, Inc.

#### California Office

Orthodontic Design and Production, Inc.  
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Vista, California USA 92081  
Telephone (760) 734-3995  
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#### Registration Information

Notified Body: BSI – Notified Body # 0086

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

#### Conformity Assessment

Applicable Council 93/42/EEC  
Directive..... (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		Part Number Prefix (Part Number begins with...)		
	Product Description				
13-380	Dental Retractors				
	Cheek Retractors		M986-*	M987-*	M993-*
	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. Sandu - Gieseemann VPO*  
Name, Title  
*M. Sandu - Gieseemann*  
Signature  
*20 March 2014*  
Date

mdi Europa GmbH

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mdiEuropa

THE MEDICAL DEVICE SERVICE-MANAGEMENT

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

~end of list~

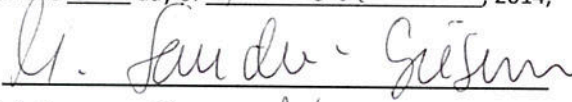
We, Orthodontic Design & Production, Inc. (ODP) of Vista, California, USA, declare with sole responsibility that the products listed above meet the essential requirements of the Council Directive 93/42/EEC (as amended) pertaining to Medical Devices. The products referenced herein are controlled by ODP's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

Signed this 10<sup>th</sup> 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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THE MEDICAL DEVICE SERVICE-MANAGEMENT