

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	Model/number
Translucent Arch Wire, Natural Arch, 0.014-inch, Upper Arch	AWS 114-U
Translucent Arch Wire, Natural Arch, 0.014-inch, Lower Arch	AWS 114-L
Translucent Arch Wire, Natural Arch, 0.016-inch, Upper Arch	AWS 116-U
Translucent Arch Wire, Natural Arch, 0.016-inch, Lower Arch	AWS 116-L
Translucent Arch Wire, Natural Arch, 0.018-inch, Upper Arch	AWS 118-U
Translucent Arch Wire, Natural Arch, 0.018-inch, Lower Arch	AWS 118-L

MANUFACTURER		
Name of company	Address	Representative
BioMers Products, LLC	3425 Radio Road, Unit 204 Naples, FL 34104 USA	George Aliphtiras

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Molenstraat 15 2513 BH The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax service@emergogroup.com

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class 1 Rule 5	Annex VII of MDD 93/42/EEC Council Directive	

BioMers Products, LLC declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices.

COMPANY REPRESENTATIVE: George Aliphtiras

TITLE: Vice President

SIGNATURE:



DATE: 26/09/2008

BioMers Products, LLC, 3425Radio Road, Unit 204, Naples, Florida, 34104
■ Website: www.biomersbraces.com ■ Email: contact@biomersbraces.com
■ Phone: (239) 262-3300 ■ Fax: (239) 262-3319