

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	Model/number
- Translucent Archwire, Natural Arch, 0.014-inch, Low Force (I), Upper	AW 114-1-U
- Translucent Archwire, Natural Arch, 0.014-inch, Low Force (I), Lower	AW 114-1-L
- Translucent Archwire, Natural Arch, 0.014-inch, High Force (II), Upper	AW 114-2-U
- Translucent Archwire, Natural Arch, 0.014-inch, High Force (II), Lower	AW 114-2-L
- Translucent Archwire, Natural Arch, 0.016-inch, Low Force (I), Upper	AW 116-1-U
- Translucent Archwire, Natural Arch, 0.016-inch, Low Force (I), Lower	AW 116-1-L
- Translucent Archwire, Natural Arch, 0.016-inch, High Force (II), Upper	AW 116-2-U
- Translucent Archwire, Natural Arch, 0.016-inch, High Force (II), Lower	AW 116-2-L
- Translucent Archwire, Natural Arch, 0.018-inch, Low Force (I) / Align A, Upper	AW 118-1-U
- Translucent Archwire, Natural Arch, 0.018-inch, Low Force (I) / Align A, Lower	AW 118-1-L
- Translucent Archwire, Natural Arch, 0.018-inch, High Force (II) / Align B, Upper	AW 118-2-U
- Translucent Archwire, Natural Arch, 0.018-inch, High Force (II) / Align B, Lower	AW 118-2-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

REGISTRATION INFORMATION	
Notified Body and ID #	CE certificate number
SGS 0120	US08/5142

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class IIa Rule 5	Annex II (excluding Section 4) of MDD 93/42/EEC Council Directive	See Technical File

BioMers Products, LLC declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.


BioMers

We Make You Smile

COMPANY REPRESENTATIVE: George J Aliphtiras

TITLE: Vice President of Operations

SIGNATURE:

A handwritten signature in black ink, appearing to read 'G. Aliphtiras', written in a cursive style.

DATE: 7/08/2009