



**DECLARATION OF CONFORMITY**  
Non-Sterile Surgical Instruments with a Measuring Function

We, AxioMed Spine Corporation, hereby declare that the distributed CE marked products, specified in the annexed product list, conform to the product(s) covered by the "CE Marking of Conformity Certificate", reference number 2119117CE02 issued on May 7, 2009 and delivered by KEMA Quality B.V., Amhem, The Netherlands, Notified Body Identification Number 0344, in accordance with Annex V in combination with Annex VII of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class I reusable non-sterile surgical instruments with a measuring function meet the provisions of the EC-Directive which apply to them.

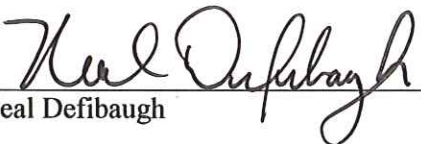
This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex V in combination with Annex VII of the EC-Directive. The conformity of the full quality assurance system set out in Annex V in combination with Annex VII, is described in the said CE Marking of Conformity Certificate, issued and delivered by KEMA Quality B.V.

This declaration is supported by the Quality System certification based on the harmonized standards ISO 13485:2003, Quality System Certificate with reference number 2113409, issued on May 2, 2008 and delivered by KEMA Registered Quality, Inc. (KRQ).

This Declaration of Conformity covers the Freedom<sup>®</sup> Lumbar Disc Non-Sterile Surgical Instruments with a Measuring Function as specified in the product list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site(s):

AxioMed Spine Corporation  
Overlook Pointe  
5350 Transportation Blvd.  
Garfield Heights, Ohio 44125  
USA

Vice President, Clinical and Regulatory Affairs

  
Neal Defibaugh

Date of Issue: May 27, 2009  
Place of Issue: AxioMed Spine Corporation  
Overlook Pointe  
5350 Transportation Blvd., Suite 18  
Garfield Heights, Ohio 44125  
USA

Declaration Number: 002B  
Annex: Product List FLD Non-Sterile Surgical Instruments with a Measuring Function

OVERLOOK POINTE  
5350 TRANSPORTATION BLVD., SUITE 18  
GARFIELD HEIGHTS, OH 44125  
OFFICE: 216.587.5566 FAX: 216.587.3388

## PRODUCT LIST

### Freedom<sup>®</sup> Lumbar Disc (FLD) Non-Sterile Surgical Instruments with a Measuring Function

This product list belongs to the Declaration of Conformity identified by AxioMed Spine Corporation and specifies the CE marked products concerned that AxioMed Spine Corporation intends to distribute in conformity the provisions of the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices. The following list identifies the FLD Non-Sterile Surgical Instruments with a Measuring Function by catalog number and description.

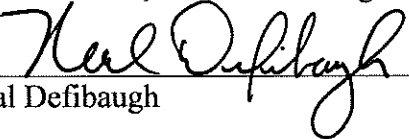
#### FLD Non-Sterile Surgical Instruments with a Measuring Function

AxioMed Catalog. N°	Designation	Class	Rule
L-TS-261104F	Disc Trial Sizer 26x36, 11 MM, 4°	I	6
L-TS-261204F	Disc Trial Sizer 26x36, 12 MM, 4°	I	6
L-TS-261304F	Disc Trial Sizer 26x36, 13 MM, 4°	I	6
L-TS-261208F	Disc Trial Sizer 26x36, 12 MM, 8°	I	6
L-TS-261308F	Disc Trial Sizer 26x36, 13 MM, 8°	I	6
L-TS-261408F	Disc Trial Sizer 26x36, 14 MM, 8°	I	6
L-TS-261508F	Disc Trial Sizer 26x36, 15, MM, 8°	I	6
L-TS-261312F	Disc Trial Sizer 26x36, 13 MM, 12°	I	6
L-TS-261412F	Disc Trial Sizer 26x36, 14 MM, 12°	I	6
L-TS-261512F	Disc Trial Sizer 26x36, 15 MM, 12°	I	6
L-TS-261612F	Disc Trial Sizer 26x36, 16 MM, 12°	I	6

Axiomed Catalog. N°	Designation	Class	Rule
L-TS-281208F	Disc Trial Sizer 28x38, 12 MM 8°	I	6
L-TS-281308F	Disc Trial Sizer 28x38, 13 MM 8°	I	6
L-TS-281408F	Disc Trial Sizer 28x38, 14 MM, 8°	I	6
L-TS-281508F	Disc Trial Sizer 28x38, 15 MM, 8°	I	6
L-TS-281312F	Disc Trial Sizer 28x38, 13 MM, 12°	I	6
L-TS-281412F	Disc Trial Sizer 28x38, 14 MM, 12°	I	6
L-TS-281512F	Disc Trial Sizer 28x38, 15 MM, 12°	I	6
L-TS-281612F	Disc Trial Sizer 28x38, 16 MM, 12°	I	6

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 USA

Vice President, Clinical and Regulatory Affairs

  
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