



DECLARATION OF CONFORMITY
Medical Devices

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 2119117CE01 issued on May 7, 2009 and delivered by KEMA Quality B.V., Amhem, The Netherlands, Notified Body Identification Number 0344, in accordance with Annex II 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 IIb, 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 II of the EC-Directive. The conformity of the full quality assurance system set out in Annex II, 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[®] Lumbar Disc 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: July 24, 2009
Place of Issue: AxioMed Spine Corporation
Overlook Pointe
5350 Transportation Blvd., Suite 18
Garfield Heights, Ohio 44125
USA

Declaration Number: 002A
Annex: Product List Freedom[®] Lumbar Disc (FLD)

PRODUCT LIST
Freedom[®] Lumbar Disc (FLD)

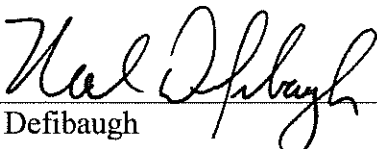
This product list belongs to the Declaration of Conformity identified by AxioMed Spine Corporation and specifies the CE marked products concerned that AxioMed Spine Corporation intends to distribute in conformity the provisions of the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices. The Freedom[®] Lumbar Disc (FLD) is available in multiple configurations to accommodate the L3-S1 lumbar anatomy. A total of nineteen (19) sizes are offered. The following list identifies the FLD by part number and description.

FLD Implant Part Numbers and Descriptions

FLD Flat Part No	Foot-Print (mm)	Anterior Height (mm)	Angle (degrees)
261104-F	26x36	14	4
261204-F	26x36	15	4
261304-F	26x36	16	4
261208-F	26x36	14	8
261308-F	26x36	15	8
261408-F	26x36	16	8
261508-F	26x36	17	8
261312-F	26x36	15	12
261412-F	26x36	16	12
261512-F	26x36	17	12
261612-F	26x36	18	12
281208-F	28x38	15	8
281308-F	28x38	16	8
281408-F	28x38	17	8
281508-F	28x38	18	8
281312-F	28x38	16	12
281412-F	28x38	17	12
281512-F	28x38	18	12
281612-F	28x38	19	12

FLD Flat Part No	Foot-Print (mm)	Anterior Height (mm)	Angle (degrees)
End Cap			

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