



## DECLARATION OF CONFORMITY

This declaration is being made in accordance with Annex II

**Product(s): Metallic Implants, See Appendix A**

**Class: IIb**

**Annex IX Rule: 8**

We,

DePuy Spine, Inc.  
325 Paramount Drive  
Raynham, MA 02767  
U.S.A.

Declare under our sole responsibility that the medical devices specified above and included in the technical file/design dossier are manufactured using a Quality System assessed and certified (MDSAP 685945 and CE 53820) by BSi (Notified Body Number 2797). These medical devices are in conformity with the standards as indicated in the Essential Requirements Checklist, following the provisions of Council Directive 93/42/EEC of June 14, 1993 current revision and amendments concerning medical devices and its subsequent transposition into the laws of the European Economic Area.

DePuy Ireland UC, Loughbeg, Ringaskiddy, County Cork, Ireland. is the authorized European Representative for DePuy Spine, Inc.

Mitchihiro  
Ohiwa

Digitally signed by Mitchihiro Ohiwa  
Reason: I attest to the accuracy and integrity of this document.  
Date: 2021.04.08 15:53:43 -04'00'  
Adobe Acrobat DC version: 2015.006.30527

Signed on behalf of DePuy Spine, Inc.

Name (of responsible representative): Mitchihiro Ohiwa

Position/Title: Associate Director, Regulatory Affairs

Technical File 1 Rev. BP