



## 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.

Signed on behalf of DePuy Spine, Inc. \_\_\_\_\_

Name (of responsible representative): Anna D'Lima

Position/Title: Manager, Regulatory Affairs

Technical File 1 Rev. BS

This Declaration of Conformity to European Medical Devices Directive 93/42/EEC has been re-issued and signed for administrative purposes. We confirm that these products were listed on a valid CE Declaration of Conformity prior to the Date of Application (26 May 2021) of Regulation (EU) 2017/745 and may continue to be placed on the market in compliance with Article 120 Transitional Provisions of the Regulation.

#### Post-May 2021 Revision History

Revision	Date of Revision	Description of Change
BQ	27 December 2021	Updated product descriptions for 76 codes per labels. Replaced obsolete GMDN codes with active ones.
BR	26 April 2022	Replaced non-sterile GMDN code [ 61325] with sterile GMDN code [ 61234 ] for 24 SKUs which were mapped wrongly before. Removed references to EN 980
BS	28 November 2022	Replaced non-sterile old GMDN code [61669] with [61325] for 24 SKU's as it is getting updated in GUDID portal.