

EU DECLARATION OF CONFORMITY to MEDICAL DEVICE REGULATION 2017/745		
Manufacturer Name:	Stryker Instruments a division of Stryker Corporation	
Manufacturer Single Registration Number (SRN):	TBD	
Manufacturer Address:	1941 Stryker Way Portage MI 49002 USA	
EU Authorized Representative Information:	Stryker European Operations Limited Anngrove, IDA Business & Technology Park, Carrigtwohill, Co. Cork T45 HX08 Ireland	
See Appendix A for Device information.		
<p>We hereby declare under our sole responsibility that these products conform with the relevant provisions of the Medical Device Regulation 2017/745.</p> <p>Each of the listed and CE Marked products in Appendix A has been verified against defined criteria and found to be in compliance with the General Safety and Performance Requirements of Annex I in the Medical Device Regulation 2017/745 prior to being placed on the market. This Declaration of Conformity is valid in conjunction with the respective production release records for the referenced devices. This declaration applies to CE Marked devices produced on or after the date issuance of this declaration and until it is superseded by another declaration or withdrawn.</p>		
Name and Identification Number of Notified Body	Description of Conformity Assessment Procedure	Issued Certificate Number
TUV Rheinland 0197	Annex IX, Chapter I, Section 2 and 3, and Chapter III of Regulation (EU) 2017/745	HZ 2247538-1
Reference to Common Specifications	Not Applicable	
Additional Information	Not Applicable	
Reviewed and Approved By	Mairead Twomey	
Function:	Senior Director, Regulatory Affairs	
Place of Issue:	Stryker Ireland Instruments	
Date of Issue:	01-Sep-2021	
Signature:	 <div style="font-size: small;"> Mairead Twomey Director, Regulatory Affairs Stryker Ireland Instruments 01-Sep-2021 </div>	

Declaration of Conformity Document Number : D0000082820

Declaration of Conformity Document Revision Number : AA



Appendix A: Device Information

Product Number	Product / Accessory Trade Name	Basic UDI-DI	Device (Risk) Class	Intended Purpose	GMDN	CND Code	CE TD Number	Initial CE Release Date
6725127105	Oscillating Tip Saw Cartridge	08858251002062S8	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000015669	17/06/2015
6720127090	Oscillating Tip Saw Cartridge	08858251002062S8	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000015669	17/06/2015
6725137105	Oscillating Tip Saw Cartridge	08858251002062S8	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000015669	17/06/2015
6425127105	Oscillating Tip Saw Cartridge	08858251002062S8	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000015669	17/06/2015
6725127090	Oscillating Tip Saw Cartridge	08858251002062S8	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000015669	04/08/2015
6720127105	Oscillating Tip Saw Cartridge	08858251002062S8	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000015669	04/08/2015
6720137105	Oscillating Tip Saw Cartridge	08858251002062S8	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000015669	25/08/2015
7812042001K	Blade Pack, 42mm	08858251002055SB	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019217	06/06/2016
7812044001K	Blade Pack, 44mm	08858251002055SB	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019217	06/06/2016
7812046001K	Blade Pack, 46mm	08858251002055SB	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019217	06/06/2016
7812048001K	Blade Pack, 48mm	08858251002055SB	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019217	06/06/2016
7812050001K	Blade Pack, 50mm	08858251002055SB	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019217	06/06/2016
7812052001K	Blade Pack, 52mm	08858251002055SB	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019217	06/06/2016
7812054001K	Blade Pack, 54mm	08858251002055SB	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019217	06/06/2016
7812056001K	Blade Pack, 56mm	08858251002055SB	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019217	06/06/2016
7812058001K	Blade Pack, 58mm	08858251002055SB	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019217	06/06/2016
7812060001K	Blade Pack, 60mm	08858251002055SB	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019217	06/06/2016
7812062001K	Blade Pack, 62mm	08858251002055SB	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019217	06/06/2016
7812064001K	Blade Pack, 64mm	08858251002055SB	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019217	06/06/2016
7812066001K	Blade Pack, 66mm	08858251002055SB	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019217	06/06/2016
7812068001K	Blade Pack, 68mm	08858251002055SB	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019217	06/06/2016
7812070001K	Blade Pack, 70mm	08858251002055SB	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019217	06/06/2016
7812072001K	Blade Pack, 72mm	08858251002055SB	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019217	06/06/2016
7812074001K	Blade Pack, 74mm	08858251002055SB	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019217	06/06/2016

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Product Number	Product / Accessory Trade Name	Basic UDI-DI	Device (Risk) Class	Intended Purpose	GMDN	CND Code	CE TD Number	Initial CE Release Date
2108100000	2108 Series Sagittal Blade (24.9 x 0.64 x 73.8mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	13/05/1991
2108102000	2108 Series Sagittal Blade (24.8 x 0.88 x 90.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/06/1991
2108105000	2108 Series Sagittal Blade (24.8 x 0.88 x 73.8mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	28/06/1991
2108109000	2108 Series Sagittal Blade (20.7 x 0.88 x 85.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/06/1991
2108110000	2108 Series Sagittal Blade (24.8 x 1.24 x 73.8mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/06/1991
2108111000	2108 Series Sagittal Blade (24.8 x 1.24 x 80.1mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	02/04/1991
2108113000	2108 Series Sagittal Blade (16.6 x 1.24 x 34.9mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	17/03/1994
2108115000	2108 Series Sagittal Blade (18.6 x 0.8 x 73.8mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/06/1991
2108118000	2108 Series Sagittal Blade, No Offset (24.8 x 1.24 x 80.1mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/06/1991
2108120000	2108 Series Sagittal Blade (18.6 x 0.64 x 61.1mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	28/05/1991
2108131000	Safedge™ 2108 Series Sagittal Blade (17.2 x 0.64 x 48.4mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	17/02/1994
2108140000	2108 Series Sagittal Blade (28.9 x 0.64 x 58.7mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/06/1991
2108144000	2108 Series Sagittal Blade (5.8 x 0.64 x 25.2mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	03/08/1993
2108145000	2108 Series Sagittal Blade (9.1 x 0.64 x 25.4mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/06/1991
2108148000	2108 Series Sagittal Blade (9.1 x 0.64 x 35.2mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/06/1991
2108150000	2108 Series Sagittal Blade (12.5 x 0.64 x 73.8mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/06/1991
2108151000	2108 Series Sagittal Blade, No Offset (24.8 x 1.19 x 85.7mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/06/1991

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2108152000	2108 Series Sagittal Blade, No Offset (12.4 x 1.19 x 82.1mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/06/1991
2108155000	2108 Series Sagittal Blade, Offset (12.4 x 1.24 x 73.7mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/06/1991
2108156000	2108 Series Sagittal Blade (12.4 x 1.24 x 80.1mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	24/06/1991
2108158000	2108 Series Sagittal Blade, No Offset (12.4 x 1.27 x 82.1mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/06/1991
2108160000	2108 Series Sagittal Blade (24.7 x 0.89 x 73.7mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	02/04/1991
2108175000	2108 Series Sagittal Blade (9.4 x 0.64 x 61.1mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/06/1991
2108176000	2108 Series Sagittal Blade, No Offset (24.8 x 1.24 x 80.1mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/01/1993
2108177000	2108 Series Sagittal Blade, No Offset (24.8 x 1.32 x 87.3mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	18/08/1993
2108182000	2108 Series Sagittal Blade, No Offset (18.6 x 1.24 x 84.4mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	02/04/1991
2108183000	2108 Series Sagittal Blade, No Offset (28.9 x 1.24 x 84.4mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	02/04/1991
2108185000	2108 Series Sagittal Blade, No Offset (18.6 x 1.24 x 105mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	07/04/1994
2108189000	2108 Series Sagittal Blade, No Offset (24.8 x 1.27 x 82.1mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	12/09/1991
4125107090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000
4125119090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	17/01/2003
4125127090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	05/07/2000
4125127100	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000
4125135090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000
4125137090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	21/05/2003
4125147090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000

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5400134005	5.0mm Caspar Blade	08858251002012RR	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019218	14/11/2007
5400134006	6.0mm Caspar Blade	08858251002012RR	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019218	02/12/2008
5400134007	7.0mm Caspar Blade	08858251002012RR	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019218	01/12/2008
5400134008	8.0mm Caspar Blade	08858251002012RR	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019218	09/04/2007
5400134009	9.0mm Caspar Blade	08858251002012RR	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019218	10/09/2010
5400134010	10.0mm Caspar Blade	08858251002012RR	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019218	03/03/2006
5400134011	11.0mm Caspar Blade	08858251002012RR	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019218	13/07/2011
5400134012	12.0mm Caspar Blade	08858251002012RR	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019218	06/09/2011
5400134013	13.0mm Caspar Blade	08858251002012RR	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019218	10/03/2011
5400134014	14.0mm Caspar Blade	08858251002012RR	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019218	24/09/2009
6118127100	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	15/08/2006
6118127110	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	11/05/2012
6118137090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	15/08/2006
6118137100	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	18/03/2010
6118147060	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	24/10/2006
6125089075	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	15/08/2006
6125089090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	15/08/2006
6125097090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	15/08/2006
6125100110	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	26/03/2009
6125107090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	05/05/2006

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6125119090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	15/08/2006
6125127090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	05/05/2006
6125127100	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	15/08/2006
6125137090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	15/08/2006
6125137100	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	26/03/2009
6125137110	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	27/01/2015
6125147090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	15/08/2006
2108103000S5	2108 Series Sagittal Blade, Colligan Special (12.5 x 0.89 x 90.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	27/06/2006
2108150000S9	2108 Series Sagittal Blade Flared (13.2 x 0.64 x 63.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	09/09/2004
6213119070	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	17/05/2011
6213127070	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	30/08/2011
6213137070	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	02/12/2011
6221100090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	18/01/2011
6221119090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	04/02/2011
6221127090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	04/02/2011
6221137090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	04/02/2011

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6221147090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	04/02/2011
2108393005S2	2108 Series Sagittal Blade (25.0 x 0.99 x 90.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	07/01/2008
6213147070	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	01/12/2015
2108127070	2108 Series Sagittal Blade (8.0 x 1.27 x 70.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	07/10/2016
2108192000	2108 Series Sagittal Rasp (20.1 x 46.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	12/09/1991
2108193000	2108 Series Sagittal Blade, No Offset (24.8 x 1.04 x 82.1mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	09/09/1994
4225089090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	30/01/2001
4225127090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	11/09/2001
4225147090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	11/09/2001
4111089090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000
4111107090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000
4111127090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000
4111135090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000
4111147075	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000
4118089090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000
4118097090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000
4118119090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	21/05/2003
4118127090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000
4118127100	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000
4118135090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000
4118137090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	23/05/2003
4125064075	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000
4125089075	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000

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4125089090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000
4125097090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000
2108103000	2108 Series Sagittal Blade (12.5 x 0.88 x 90.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	09/09/1994
2108107001	2108 Series Sagittal Blade Fan, Offset (29.0 x 0.89 x 73.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	01/03/2001
2108107004	2108 Series Sagittal Blade Fan, Offset (36.0 x 1.2 x 64.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	17/05/2001
2108107005	2108 Series Sagittal Blade Fan, Ground (29.0 x 1.24 x 84.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	23/11/2004
2108107009	2108 Series Sagittal Blade Fan, Offset (34.5 x 0.8 x 64.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	19/01/2001
2108109001	2108 Series Sagittal Blade, Offset (20.5 x 0.89 x 94.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	19/10/2006
2108109003	2108 Series Sagittal Blade, Offset (20.0 x 0.89 x 80.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	17/04/2003
2108109004	2108 Series Sagittal Blade, Ground (20.5 x 1.27 x 85.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	03/10/2000
2108110002	2108 Series Sagittal Blade, Ground (25.0 x 1.24 x 89.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	21/02/2001
2108110006	2108 Series Sagittal Blade, Ground (25.0 x 1.24 x 90.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	07/08/2001
2108120006	2108 Series Sagittal Blade, Offset (18.5 x 0.64 x 63.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	29/04/2003
2108120009	2108 Series Sagittal Blade, Ground (18.5 x 1.24 x 60.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	18/05/2004
2108130001	2108 Series Sagittal Blade, Offset (25.0 x 0.64 x 47.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	14/10/2003
2108140006	2108 Series Sagittal Blade Flared, Offset (31.0 x 0.64 x 63.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	16/02/2001
2108145001	2108 Series Sagittal Blade, Offset (9.0 x 0.64 x 24.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	18/06/2001

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Product Number	Product / Accessory Trade Name	Basic UDI-DI	Device (Risk) Class	Intended Purpose	GMDN	CND Code	CE TD Number	Initial CE Release Date
2108146000	2108 Series Sagittal Blade (6.6 x 0.64 x 26.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	19/11/2012
2108148003	2108 Series Sagittal Blade, Offset (9.0 x 0.38 x 22.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	07/12/2000
2108151001	2108 Series Sagittal Blade, Ground (25.0 x 1.19 x 95.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	14/12/1999
2108152002	2108 Series Sagittal Blade, Ground (12.5 x 1.19 x 61.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	08/11/2004
2108152006	2108 Series Sagittal Blade, Ground (12.5 x 0.89 x 88.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	01/03/2001
2108158002	2108 Series Sagittal Blade, Ground (12.5 x 1.27 x 73.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	06/02/2002
2108161002	2108 Series Sagittal Blade, Offset (27.0 x 1.24 x 73.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	07/08/2001
2108176001	2108 Series Sagittal Blade, Ground (25.0 x 1.47 x 98.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	29/11/1999
2108176002	2108 Series Sagittal Blade, Ground (25.0 x 1.47 x 93.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	29/11/1999
2108176003	2108 Series Sagittal Blade, Ground (25.0 x 1.47 x 85.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	16/03/2007
2108177001	2108 Series Sagittal Blade, Ground (25.0 x 1.32 x 82.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	15/03/2011
2108182006	2108 Series Sagittal Blade, Ground (18.5 x 1.32 x 86.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	11/09/2001
2108182008	2108 Series Sagittal Blade, Ground (18.5 x 1.24 x 73.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	22/01/2002
2108182010	2108 Series Sagittal Blade, Ground (19.1 x 1.32 x 98.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	10/06/2010
2108183001	2108 Series Sagittal Blade Flared, Ground (29.0 x 0.97 x 84.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	11/09/2001
2108183003	2108 Series Sagittal Blade Flared, Ground (29.0 x 1.32 x 84.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	04/08/2003

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Product Number	Product / Accessory Trade Name	Basic UDI-DI	Device (Risk) Class	Intended Purpose	GMDN	CND Code	CE TD Number	Initial CE Release Date
2108183013	2108 Series Sagittal Blade Flared, Ground (25.0 x 1.27 x 99.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	03/11/1999
2108185001	2108 Series Sagittal Blade, Ground (18.5 x 1.24 x 104.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	18/06/2001
2108185002	2108 Series Sagittal Blade, Ground (18.5 x 1.27 x 99.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	03/11/1999
2108195000	2108 Series Sagittal Blade Flared (48.1 x 0.97 x 90.7mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	09/09/1994
2108197000	2108 Series Sagittal Blade Flared (48.1 x 0.64 x 61.7mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	09/09/1994
2108218000	2108 Series Sagittal Blade (24.8 x 1.24 x 99.2mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	09/03/1994
2108302000	2108 Series Sagittal Blade Aggressive (25.0 x 0.89 x 89.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	06/10/1995
2108305000	2108 Series Sagittal Blade Aggressive (25.0 x 0.89 x 73.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	06/10/1995
2108309000	2108 Series Sagittal Blade Aggressive (21.0 x 0.89 x 84.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	06/10/1995
2108310000	2108 Series Sagittal Blade Aggressive (25.0 x 1.24 x 73.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	06/10/1995
2108318000	2108 Series Sagittal Blade Aggressive (25.0 x 1.24 x 79.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/10/1995
2108328000	2108 Series Sagittal Blade Aggressive (25.0 x 1.24 x 98.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	04/12/1995
2108351000	2108 Series Sagittal Blade Aggressive (25.0 x 1.19 x 85.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	06/10/1995

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Product Number	Product / Accessory Trade Name	Basic UDI-DI	Device (Risk) Class	Intended Purpose	GMDN	CND Code	CE TD Number	Initial CE Release Date
2108351002	2108 Series Sagittal Blade Flared, Ground (25.0 x 1.2 x 95.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	04/08/2003
2108352000	2108 Series Sagittal Blade Aggressive (12.5 x 1.19 x 81.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	06/10/1995
2108356000	2108 Series Sagittal Blade Aggressive (12.5 x 1.24 x 79.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	01/12/1995
2108376000	2108 Series Sagittal Blade Aggressive (25.0 x 1.47 x 79.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	13/11/1995
2108376002	2108 Series Sagittal Blade, Ground (25.0 x 1.27 x 91.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	30/03/2004
2108377000	2108 Series Sagittal Blade Aggressive (25.0 x 1.32 x 86.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	06/10/1995
2108382000	2108 Series Sagittal Blade Aggressive (18.5 x 1.24 x 83.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	13/11/1995
2108382001	2108 Series Sagittal Blade Flared, Ground (18.5 x 1.32 x 90.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	08/11/2004
2108382002	2108 Series Sagittal Blade Flared, Ground (19.0 x 1.37 x 90.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	17/09/2008
2108382003	2108 Series Sagittal Blade Flared, Ground (18.5 x 1.27 x 90.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	19/01/2009
2108383000	2108 Series Sagittal Blade Aggressive Flared (29.0 x 1.24 x 83.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	06/10/1995
2108383002	2108 Series Sagittal Blade Aggressive Flared (25.4 x 1.28 x 91.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	13/04/2012

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Product Number	Product / Accessory Trade Name	Basic UDI-DI	Device (Risk) Class	Intended Purpose	GMDN	CND Code	CE TD Number	Initial CE Release Date
2108385000	2108 Series Sagittal Blade Aggressive (18.5 x 1.24 x 104.0mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	22/05/1996
2108389000	2108 Series Sagittal Blade Aggressive (25.0 x 1.27 x 81.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	06/10/1995
2108393000	2108 Series Sagittal Blade Aggressive (25.0 x 1.04 x 81.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	01/12/1995
2108393005	2108 Series Sagittal Blade Flared, Ground (25.0 x 0.96 x 89.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	29/11/1999
2108393006	2108 Series Sagittal Blade, Ground (25.0 x 0.96 x 90.5mm)	08858251002061S6	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	29/11/1999
5301110051	Heavy Duty Sagittal Blade (32.0 x 0.6 x 62.8mm)	08858251002049SG	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	06/10/2015
4111089075	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	03/01/2007
4111119090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	17/10/2005
4118089075	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	20/09/2000
4118107090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	13/02/2012
4118127075	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	10/05/2005
4118147090	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	27/04/2007
4211127075	Dual Cut Sagittal Blade, Flared	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	23/09/2009
4218147060	Dual Cut Sagittal Blade, No Offset	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	26/09/2008
4221120085	Dual Cut Sagittal Blade	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	04/03/2009
4221140090	Dual Cut Sagittal Blade, No Offset	08858251002059SK	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	26/06/2008
6113089090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	15/08/2006
6113107090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	15/08/2006

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Product Number	Product / Accessory Trade Name	Basic UDI-DI	Device (Risk) Class	Intended Purpose	GMDN	CND Code	CE TD Number	Initial CE Release Date
6113119090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	08/10/2010
6113127060	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	09/08/2011
6113127075	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	23/04/2012
6113127090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	05/05/2006
6113127100	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	12/08/2009
6113137090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	15/08/2006
6113137100	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	27/08/2012
6113147090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	05/02/2009
6118089075	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	15/08/2006
6118089090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	17/10/2006
6118097090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	15/08/2006
6118119090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	15/08/2006
6118119100	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	03/06/2010
6118119110	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	09/08/2011
6118127075	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	24/02/2009
6118127090	Stryker Performance Series® Sagittal Blade	08858251002060S4	Class IIa	Bone Cutting and drilling devices	43376	V0103	D0000019220	15/08/2006

Appendix B: Revision History

Revision	Description of Change	Date
AA	Initial release to onePLM as D0000082820. Parts moved over from DOC D0000019479 to MDR template to declare products in scope to MDR compliance. DoC renamed to DoC_MDR_Bone Cutting and Drilling Devices Class IIA V0103.	See onePLM







DoC_MDR_Bone Cutting and Drilling Devices Class IIa V0103 Rev AA

Final Audit Report

2021-09-01

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By:	Josh Measures (josh.measures@stryker.com)
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"DoC_MDR_Bone Cutting and Drilling Devices Class IIa V0103 Rev AA" History

-  Document created by Josh Measures (josh.measures@stryker.com)
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