

EC DECLARATION OF CONFORMITY

In accordance with Council Directive 93/42/EEC on medical devices.

Manufacturer Information:

Manufacturer: Global Biomedica s.r.o.

Registered office: Ostravska 555/24, 737 01 Cesky Tesin, Czech Republic

Product Identification:

Brand name: BMD Titanium Implant

<i>MODEL</i>	<i>REF</i>
BMD Titanium ACIF Implant	BMDA10120400,BMDA10120500,BMDA10120600,BMDA10120700,BMDA10120800, BMDA10120900,BMDA12140400,BMDA12140500,BMDA12140600,BMDA12140700, BMDA12140800,BMDA12140900,BMDA14160400,BMDA14160500,BMDA14160600, BMDA14160700,BMDA14160800,BMDA14160900,BMDA10120405,BMDA10120505, BMDA10120605,BMDA10120705,BMDA10120805,BMDA10120905,BMDA12140405, BMDA12140505,BMDA12140605,BMDA12140705,BMDA12140805,BMDA12140905, BMDA14160405,BMDA14160505,BMDA14160605,BMDA14160705,BMDA14160805, BMDA14160905,BMDA15180505,BMDA15180605,BMDA15180705,BMDA15180805, BMDA15180905,BMDA15181005,BMDA16180505,BMDA16180605,BMDA16180705, BMDA16180805,BMDA16180905,BMDA16181005,BMDA12140510,BMDA12140610, BMDA12140710,BMDA12140810,BMDA12140910,BMDA12141010,BMDA14160510, BMDA14160610,BMDA14160710,BMDA14160810,BMDA14160910,BMDA14161010, BMDA15180510,BMDA15180610,BMDA15180710,BMDA15180810,BMDA15180910, BMDA15181010,BMDA16180510,BMDA16180610,BMDA16180710,BMDA16180810, BMDA16180910,BMDA16181010
BMD Titanium ACIF GW Implant	BMDC10120400,BMDC10120500,BMDC10120600,BMDC10120700,BMDC10120800, BMDC10120900,BMDC12140400,BMDC12140500,BMDC12140600,BMDC12140700, BMDC12140800,BMDC12140900,BMDC14160400,BMDC14160500,BMDC14160600, BMDC14160700,BMDC14160800,BMDC14160900,BMDC10120405,BMDC10120505, BMDC10120605,BMDC10120705,BMDC10120805,BMDC10120905,BMDC12140405, BMDC12140505,BMDC12140605,BMDC12140705,BMDC12140805,BMDC12140905, BMDC14160405,BMDC14160505,BMDC14160605,BMDC14160705,BMDC14160805, BMDC14160905,BMDC15180505,BMDC15180605,BMDC15180705,BMDC15180805, BMDC15180905,BMDC15181005,BMDC16180505,BMDC16180605,BMDC16180705, BMDC16180805,BMDC16180905,BMDC16181005,BMDC12140510,BMDC12140610, BMDC12140710,BMDC12140810,BMDC12140910,BMDC12141010,BMDC14160510, BMDC14160610,BMDC14160710,BMDC14160810,BMDC14160910,BMDC14161010, BMDC15180510,BMDC15180610,BMDC15180710,BMDC15180810,BMDC15180910, BMDC15181010,BMDC16180510,BMDC16180610,BMDC16180710,BMDC16180810, BMDC16180910,BMDC16181010

<p>BMD Titanium PLIF Implant</p>	<p>BMDP33120700,BMDP33120800,BMDP33120900,BMDP33121000,BMDP33121100, BMDP33121200,BMDP33121300,BMDP33121400,BMDP33121500,BMDP20090704, BMDP20090804,BMDP20090904,BMDP20091004,BMDP20091104,BMDP20091204, BMDP20091304,BMDP20091404,BMDP20091504,BMDP20091604,BMDP20091704, BMDP24090704,BMDP24090804,BMDP24090904,BMDP24091004,BMDP24091104, BMDP24091204,BMDP24091304,BMDP24091404,BMDP24091504,BMDP24091604, BMDP24091704,BMDP24100704,BMDP24100804,BMDP24100904,BMDP24101004, BMDP24101104,BMDP24101204,BMDP24101304,BMDP24101404,BMDP24101504, BMDP24101604,BMDP24101704,BMDP28090704,BMDP28090804,BMDP28090904, BMDP28091004,BMDP28091104,BMDP28091204,BMDP28091304,BMDP28091404, BMDP28091504,BMDP28091604,BMDP28091704,BMDP28100704,BMDP28100804, BMDP28100904,BMDP28101004,BMDP28101104,BMDP28101204,BMDP28101304, BMDP28101404,BMDP28101504,BMDP28101604,BMDP28101704,BMDP33120904, BMDP33121104,BMDP33121304,BMDP33121504,BMDP20090708,BMDP20090808, BMDP20090908,BMDP20091008,BMDP20091108,BMDP20091208,BMDP20091308, BMDP20091408,BMDP20091508,BMDP20091608,BMDP20091708,BMDP24090708, BMDP24090808,BMDP24090908,BMDP24091008,BMDP24091108,BMDP24091208, BMDP24091308,BMDP24091408,BMDP24091508,BMDP24091608,BMDP24091708, BMDP24100708,BMDP24100808,BMDP24100908,BMDP24101008,BMDP24101108, BMDP24101208,BMDP24101308,BMDP24101408,BMDP24101508,BMDP24101608, BMDP24101708,BMDP28090708,BMDP28090808,BMDP28090908,BMDP28091008, BMDP28091108,BMDP28091208,BMDP28091308,BMDP28091408,BMDP28091508, BMDP28091608,BMDP28091708,BMDP28100708,BMDP28100808,BMDP28100908, BMDP28101008,BMDP28101108,BMDP28101208,BMDP28101308,BMDP28101408, BMDP28101508,BMDP28101608,BMDP28101708,BMDP33120908,BMDP33121008, BMDP33121108,BMDP33121208,BMDP33121308,BMDP33121408,BMDP33121508, BMDP20090712,BMDP20090812,BMDP20090912,BMDP20091012,BMDP20091112, BMDP20091212,BMDP20091312,BMDP20091412,BMDP20091512,BMDP20091612, BMDP20091712,BMDP24090912,BMDP24091012,BMDP24091112,BMDP24091212, BMDP24091312,BMDP24091412,BMDP24091512,BMDP24091612,BMDP24091712, BMDP24100912,BMDP24101012,BMDP24101112,BMDP24101212,BMDP24101312, BMDP24101412,BMDP24101512,BMDP24101612,BMDP24101712,BMDP28091112, BMDP28091212,BMDP28091312,BMDP28091412,BMDP28091512,BMDP28091612, BMDP28091712,BMDP28101112,BMDP28101212,BMDP28101312,BMDP28101412, BMDP28101512,BMDP28101612,BMDP28101712,BMDP33121112,BMDP33121212, BMDP33121312,BMD033121412,BMDP33121512,BMDP33121612,BMDP33121712, BMDP20090716,BMDP20090816,BMDP20090916,BMDP20091016,BMDP20091116, BMDP20091216,BMDP20091316,BMDP20091416,BMDP20091516,BMDP20091616, BMDP20091716,BMDP24091116,BMDP24091216,BMDP24091316,BMDP24091416, BMDP24091516,BMDP24091616,BMDP24091716,BMDP24101116,BMDP24101216, BMDP24101316,BMDP24101416,BMDP24101516,BMDP24101616,BMDP24101716, BMDP28091316,BMDP28091416,BMDP28091516,BMDP28091616,BMDP28091716, BMDP28101316,BMDP28101416,BMDP28101516,BMDP28101616,BMDP28101716, BMDP20090920,BMDP20091020,BMDP20091120,BMDP20091220,BMDP20091320, BMDP20091420,BMDP20091520,BMDP20091620,BMDP20091720,BMDP24091320, BMDP24091420,BMDP24091520,BMDP24091620,BMDP24091720,BMDP24101320, BMDP24101420,BMDP24101520,BMDP24101620,BMDP24101720,BMDP28091520, BMDP28091620,BMDP28091720,BMDP28101520,BMDP28101620,BMDP28101720</p>
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<p>BMD Titanium PLIF GW Implant</p>	<p>BMDH33120700,BMDH33120800,BMDH33120900,BMDH33121000,BMDH33121100, BMDH33121200,BMDH33121300,BMDH33121400,BMDH33121500,BMDH20090704, BMDH20090804,BMDH20090904,BMDH20091004,BMDH20091104,BMDH20091204, BMDH20091304,BMDH20091404,BMDH20091504,BMDH20091604,BMDH20091704, BMDH24090704,BMDH24090804,BMDH24090904,BMDH24091004,BMDH24091104, BMDH24091204,BMDH24091304,BMDH24091404,BMDH24091504,BMDH24091604, BMDH24091704,BMDH24100704,BMDH24100804,BMDH24100904,BMDH24101004, BMDH24101104,BMDH24101204,BMDH24101304,BMDH24101404,BMDH24101504, BMDH24101604,BMDH24101704,BMDH28090704,BMDH28090804,BMDH28090904, BMDH28091004,BMDH28091104,BMDH28091204,BMDH28091304,BMDH28091404, BMDH28091504,BMDH28091604,BMDH28091704,BMDH28100704,BMDH28100804, BMDH28100904,BMDH28101004,BMDH28101104,BMDH28101204,BMDH28101304, BMDH28101404,BMDH28101504,BMDH28101604,BMDH28101704,BMDH33120904, BMDH33121104,BMDH33121304,BMDH33121504,BMDH20090708,BMDH20090808, BMDH20090908,BMDH20091008,BMDH20091108,BMDH20091208,BMDH20091308, BMDH20091408,BMDH20091508,BMDH20091608,BMDH20091708,BMDH24090708, BMDH24090808,BMDH24090908,BMDH24091008,BMDH24091108,BMDH24091208, BMDH24091308,BMDH24091408,BMDH24091508,BMDH24091608,BMDH24091708, BMDH24100708,BMDH24100808,BMDH24100908,BMDH24101008,BMDH24101108, BMDH24101208,BMDH24101308,BMDH24101408,BMDH24101508,BMDH24101608, BMDH24101708,BMDH28090708,BMDH28090808,BMDH28090908,BMDH28091008, BMDH28091108,BMDH28091208,BMDH28091308,BMDH28091408,BMDH28091508, BMDH28091608,BMDH28091708,BMDH28100708,BMDH28100808,BMDH28100908, BMDH28101008,BMDH28101108,BMDH28101208,BMDH28101308,BMDH28101408, BMDH28101508,BMDH28101608,BMDH28101708,BMDH33120908,BMDH33121008, BMDH33121108,BMDH33121208,BMDH33121308,BMDH33121408,BMDH33121508, BMDH20090712,BMDH20090812,BMDH20090912,BMDH20091012,BMDH20091112, BMDH20091212,BMDH20091312,BMDH20091412,BMDH20091512,BMDH20091612, BMDH20091712,BMDH24090912,BMDH24091012,BMDH24091112,BMDH24091212, BMDH24091312,BMDH24091412,BMDH24091512,BMDH24091612,BMDH24091712, BMDH24100912,BMDH24101012,BMDH24101112,BMDH24101212,BMDH24101312, BMDH24101412,BMDH24101512,BMDH24101612,BMDH24101712,BMDH28091112, BMDH28091212,BMDH28091312,BMDH28091412,BMDH28091512,BMDH28091612, BMDH28091712,BMDH28101112,BMDH28101212,BMDH28101312,BMDH28101412, BMDH28101512,BMDH28101612,BMDH28101712,BMDH33121112,BMDH33121212, BMDH33121312,BMD033121412,BMDH33121512,BMDH33121612,BMDH33121712, BMDH20090716,BMDH20090816,BMDH20090916,BMDH20091016,BMDH20091116, BMDH20091216,BMDH20091316,BMDH20091416,BMDH20091516,BMDH20091616, BMDH20091716,BMDH24091116,BMDH24091216,BMDH24091316,BMDH24091416, BMDH24091516,BMDH24091616,BMDH24091716,BMDH24101116,BMDH24101216, BMDH24101316,BMDH24101416,BMDH24101516,BMDH24101616,BMDH24101716, BMDH28091316,BMDH28091416,BMDH28091516,BMDH28091616,BMDH28091716, BMDH28101316,BMDH28101416,BMDH28101516,BMDH28101616,BMDH28101716, BMDH20090920,BMDH20091020,BMDH20091120,BMDH20091220,BMDH20091320, BMDH20091420,BMDH20091520,BMDH20091620,BMDH20091720,BMDH24091320, BMDH24091420,BMDH24091520,BMDH24091620,BMDH24091720,BMDH24101320, BMDH24101420,BMDH24101520,BMDH24101620,BMDH24101720,BMDH28091520, BMDH28091620,BMDH28091720,BMDH28101520,BMDH28101620,BMDH28101720</p>
<p>BMD Titanium TLIF Implant</p>	<p>BMDT26100700,BMDT26100800,BMDT26100900,BMDT26101000,BMDT26101100, BMDT26101200,BMDT26101300,BMDT26101400,BMDT26101500,BMDT26101600, BMDT26101700,BMDT30110700,BMDT30110800,BMDT30110900,BMDT30111000, BMDT30111100,BMDT30111200,BMDT30111300,BMDT30111400,BMDT30111500, BMDT30111600,BMDT30111700,BMDT34120700,BMDT34120800,BMDT34120900, BMDT34121000,BMDT34121100,BMDT34121200,BMDT34121300,BMDT34121400, BMDT34121500,BMDT34121600,BMDT34121700,BMDT26100704,BMDT26100804, BMDT26100904,BMDT26101004,BMDT26101104,BMDT26101204,BMDT26101304, BMDT26101404,BMDT26101504,BMDT26101604,BMDT26101704,BMDT30110704, BMDT30110804,BMDT30110904,BMDT30111004,BMDT30111104,BMDT30111204, BMDT30111304,BMDT30111404,BMDT30111504,BMDT30111604,BMDT30111704, BMDT34120704,BMDT34120804,BMDT34120904,BMDT34121004,BMDT34121104, BMDT34121204,BMDT34121304,BMDT34121404,BMDT34121504,BMDT34121604, BMDT34121704,BMDT26100708,BMDT26100808,BMDT26100908,BMDT26101008, BMDT26101108,BMDT26101208,BMDT26101308,BMDT26101408,BMDT26101508, BMDT26101608,BMDT26101708,BMDT30110708,BMDT30110808,BMDT30110908, BMDT30111008,BMDT30111108,BMDT30111208,BMDT30111308,BMDT30111408, BMDT30111508,BMDT30111608,BMDT30111708,BMDT34120708,BMDT34120808, BMDT34120908,BMDT34121008,BMDT34121108,BMDT34121208,BMDT34121308, BMDT34121408,BMDT34121508,BMDT34121608,BMDT34121708,BMDT26100912, BMDT26101012,BMDT26101112,BMDT26101212,BMDT26101312,BMDT26101412, BMDT26101512,BMDT26101612,BMDT26101712,BMDT30110912,BMDT30111012, BMDT30111112,BMDT30111212,BMDT30111312,BMDT30111412,BMDT30111512, BMDT30111612,BMDT30111712,BMDT34120912,BMDT34121012,BMDT34121112, BMDT34121212,BMDT34121312,BMDT34121412,BMDT34121512,BMDT34121612, BMDT34121712</p>

<p>BMD Titanium TLIF GW Implant</p>	<p>BMD026100700,BMD026100800,BMD026100900,BMD026101000,BMD026101100, BMD026101200,BMD026101300,BMD026101400,BMD026101500,BMD026101600, BMD026101700,BMD030110700,BMD030110800,BMD030110900,BMD030111000, BMD030111100,BMD030111200,BMD030111300,BMD030111400,BMD030111500, BMD030111600,BMD030111700,BMD034120700,BMD034120800,BMD034120900, BMD034121000,BMD034121100,BMD034121200,BMD034121300,BMD034121400, BMD034121500,BMD034121600,BMD034121700,BMD026100704,BMD026100804, BMD026100904,BMD026101004,BMD026101104,BMD026101204,BMD026101304, BMD026101404,BMD026101504,BMD026101604,BMD026101704,BMD030110704, BMD030110804,BMD030110904,BMD030111004,BMD030111104,BMD030111204, BMD030111304,BMD030111404,BMD030111504,BMD030111604,BMD030111704, BMD034120704,BMD034120804,BMD034120904,BMD034121004,BMD034121104, BMD034121204,BMD034121304,BMD034121404,BMD034121504,BMD034121604, BMD034121704,BMD026100708,BMD026100808,BMD026100908,BMD026101008, BMD026101108,BMD026101208,BMD026101308,BMD026101408,BMD026101508, BMD026101608,BMD026101708,BMD030110708,BMD030110808,BMD030110908, BMD030111008,BMD030111108,BMD030111208,BMD030111308,BMD030111408, BMD030111508,BMD030111608,BMD030111708,BMD034120708,BMD034120808, BMD034120908,BMD034121008,BMD034121108,BMD034121208,BMD034121308, BMD034121408,BMD034121508,BMD034121608,BMD034121708,BMD026100912, BMD026101012,BMD026101112,BMD026101212,BMD026101312,BMD026101412, BMD026101512,BMD026101612,BMD026101712,BMD030110912,BMD030111012, BMD030111112,BMD030111212,BMD030111312,BMD030111412,BMD030111512, BMD030111612,BMD030111712,BMD034120912,BMD034121012,BMD034121112, BMD034121212,BMD034121312,BMD034121412,BMD034121512,BMD034121612, BMD034121712</p>
<p>BMD Titanium ALIF Implant</p>	<p>BMDL24320905,BMDL24321105,BMDL24321305,BMDL24321505,BMDL24321705, BMDL24321905,BMDL27360905,BMDL27361105,BMDL27361305,BMDL27361505, BMDL27361705,BMDL27361905,BMDL30400905,BMDL30401105,BMDL30401305, BMDL30401505,BMDL30401705,BMDL30401905,BMDL24321110,BMDL24321310, BMDL24321510,BMDL24321710,BMDL24321910,BMDL27361110,BMDL27361310, BMDL27361510,BMDL27361710,BMDL27361910,BMDL30401110,BMDL30401310, BMDL30401510,BMDL30401710,BMDL30401910,BMDL24321115,BMDL24321315, BMDL24321515,BMDL24321715,BMDL24321915,BMDL27361115,BMDL27361315, BMDL27361515,BMDL27361715,BMDL27361915,BMDL30401115,BMDL30401315, BMDL30401515,BMDL30401715,BMDL30401915,BMDL24321320,BMDL24321520, BMDL24321720,BMDL24321920,BMDL27361320,BMDL27361520,BMDL27361720, BMDL27361920,BMDL30401320,BMDL30401520,BMDL30401720,BMDL30401920</p>

BMD Titanium LLIF Implant	BMDX40180700,BMDX40180900,BMDX40181100,BMDX40181300,BMDX40181500, BMDX40181700,BMDX45180700,BMDX45180900,BMDX45181100,BMDX45181300, BMDX45181500,BMDX45181700,BMDX50180700,BMDX50180900,BMDX50181100, BMDX50181300,BMDX50181500,BMDX50181700,BMDX55180700,BMDX55180900, BMDX55181100,BMDX55181300,BMDX55181500,BMDX55181700,BMDX60180700, BMDX60180900,BMDX60181100,BMDX60181300,BMDX60181500,BMDX60181700, BMDX40220700,BMDX40220900,BMDX40221100,BMDX40221300,BMDX40221500, BMDX40221700,BMDX45220700,BMDX45220900,BMDX45221100,BMDX45221300, BMDX45221500,BMDX45221700,BMDX50220700,BMDX50220900,BMDX50221100, BMDX50221300,BMDX50221500,BMDX50221700,BMDX55220700,BMDX55220900, BMDX55221100,BMDX55221300,BMDX55221500,BMDX55221700,BMDX60220700, BMDX60220900,BMDX60221100,BMDX60221300,BMDX60221500,BMDX60221700, BMDX40180706,BMDX40180906,BMDX40181106,BMDX40181306,BMDX40181506, BMDX40181706,BMDX45180706,BMDX45180906,BMDX45181106,BMDX45181306, BMDX45181506,BMDX45181706,BMDX50180706,BMDX50180906,BMDX50181106, BMDX50181306,BMDX50181506,BMDX50181706,BMDX55180706,BMDX55180906, BMDX55181106,BMDX55181306,BMDX55181506,BMDX55181706,BMDX60180706, BMDX60180906,BMDX60181106,BMDX60181306,BMDX60181506,BMDX60181706, BMDX40220706,BMDX40220906,BMDX40221106,BMDX40221306,BMDX40221506, BMDX40221706,BMDX45220706,BMDX45220906,BMDX45221106,BMDX45221306, BMDX45221506,BMDX45221706,BMDX50220706,BMDX50220906,BMDX50221106, BMDX50221306,BMDX50221506,BMDX50221706,BMDX55220706,BMDX55220906, BMDX55221106,BMDX55221306,BMDX55221506,BMDX55221706,BMDX60220706, BMDX60220906,BMDX60221106,BMDX60221306,BMDX60221506,BMDX60221706, BMDX40180712,BMDX40180912,BMDX40181112,BMDX40181312,BMDX40181512, BMDX40181712,BMDX45180712,BMDX45180912,BMDX45181112,BMDX45181312, BMDX45181512,BMDX45181712,BMDX50180712,BMDX50180912,BMDX50181112, BMDX50181312,BMDX50181512,BMDX50181712,BMDX55180712,BMDX55180912, BMDX55181112,BMDX55181312,BMDX55181512,BMDX55181712,BMDX60180712, BMDX60180912,BMDX60181112,BMDX60181312,BMDX60181512,BMDX60181712, BMDX40220712,BMDX40220912,BMDX40221112,BMDX40221312,BMDX40221512, BMDX40221712,BMDX45220712,BMDX45220912,BMDX45221112,BMDX45221312, BMDX45221512,BMDX45221712,BMDX50220712,BMDX50220912,BMDX50221112, BMDX50221312,BMDX50221512,BMDX50221712,BMDX55220712,BMDX55220912, BMDX55221112,BMDX55221312,BMDX55221512,BMDX55221712,BMDX60220712, BMDX60220912,BMDX60221112,BMDX60221312,BMDX60221512,BMDX60221712, BMDX40200903,BMDX40201103,BMDX40201303,BMDX40201503,BMDX40201703, BMDX45200903,BMDX45201103,BMDX45201303,BMDX45201503,BMDX45201703, BMDX50200903,BMDX50201103,BMDX50201303,BMDX50201503,BMDX50201703, BMDX55200903,BMDX55201103,BMDX55201303,BMDX55201503,BMDX55201703, BMDX40200910,BMDX40201110,BMDX40201310,BMDX40201510,BMDX40201710, BMDX45200910,BMDX45201110,BMDX45201310,BMDX45201510,BMDX45201710, BMDX50200910,BMDX50201110,BMDX50201310,BMDX50201510,BMDX50201710, BMDX55200910,BMDX55201110,BMDX55201310,BMDX55201510,BMDX55201710
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Intended use: Into-tissue implant. Medical device serves as an intervertebral disc replacement.

Class of medical device: IIb

The manufacturer declares that the medical device meets the essential requirements of Directive 93/42/EEC and that the medical device is safe, effective and suitable for the purpose of providing healthcare for the intended purpose. The manufacturer further declares that the conformity according to Annex II without point 4 to Directive 93/42/EEC has been assessed.

Notified body: on the conformity assessment notified body No. 1014 – Elektrotechnickýkusebníustav, s.p. was included. Notified body has issued the certificate No. MED 190013 valid until 26.05.2024.

In Cesky Tesin, on 28.04.2021

Verified: 28.04.2021



Piotr Koziet
 Managing director
 Global Biomedica s.r.o.