

THÔNG TIN

Hồ sơ công bố tiêu chuẩn áp dụng của trang thiết bị y tế thuộc loại B

Số công bố: 220001503/PCBB-HCM

Ngày công bố: 10/05/2022

1. Tên cơ sở công bố: CÔNG TY TNHH IBS IMPLANT VIỆT NAM
2. Địa chỉ: Phòng 401 Lầu 4 A4, tòa nhà Phú Mã Dương, số 85 đường Hoàng Văn Thái, Khu TTTM Tài Chính Quốc Tế Phú Mỹ Hưng, Phường Tân Phú, Quận 7, Thành phố Hồ Chí Minh, Việt Nam, Phường Tân Phú, Quận 7, Thành phố Hồ Chí Minh
3. Số văn bản của cơ sở: IBS012022-06 Ngày: 06/05/2022
4. Trang thiết bị y tế thuộc loại B
Tên trang thiết bị y tế: Hệ thống cấy ghép Implant MagiCore
Tên thương mại:
Mã Global Medical Device Nomenclature – GMDN (nếu có):
Chủng loại: Theo phụ lục
Mã sản phẩm (nếu có): Theo phụ lục
Quy cách đóng gói:
Mục đích sử dụng: Hệ thống cấy ghép giúp phục hồi chức năng và phục hình thẩm mỹ cho răng bị mất
Tên cơ sở sản xuất: Theo phụ lục
Địa chỉ cơ sở sản xuất: Theo phụ lục
Tiêu chuẩn chất lượng sản phẩm áp dụng: ISO 13485:2016
5. Đối với trang thiết bị y tế chứa chất ma túy, tiền chất (nếu có):
6. Thông tin về chủ sở hữu trang thiết bị y tế:
Tên chủ sở hữu: Innobiosurg Co., Ltd., Korea
Địa chỉ chủ sở hữu: 44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea
7. Thông tin về cơ sở bảo hành (nếu có):
Tên cơ sở: IBS IMPLANT VIETNAM CO.,LTD

Địa chỉ: P.401 Lầu 4 A4, Tòa nhà Phú Mã Dương, 85 Hoàng Văn Thái, TTTM TC QT Phú Mỹ Hưng, P.Tân Phú, Q.7, HCM, Vietnam, Phường Tân Phú, Quận 7, Thành phố Hồ Chí Minh

Điện thoại cố định: 02822446468 Điện thoại di động:

8. Số công bố đủ điều kiện sản xuất đối với trang thiết bị y tế sản xuất trong nước:

9. Thành phần hồ sơ:

1	Văn bản công bố tiêu chuẩn áp dụng đối với trang thiết bị y tế thuộc loại B	x
2	Giấy chứng nhận đạt tiêu chuẩn quản lý chất lượng ISO 13485	x
3	Giấy ủy quyền của chủ sở hữu trang thiết bị y tế	x
4	Giấy xác nhận đủ điều kiện bảo hành	x
5	Tài liệu mô tả tóm tắt kỹ thuật trang thiết bị y tế bằng tiếng Việt	x
6	Bản tiêu chuẩn mà chủ sở hữu trang thiết bị y tế công bố áp dụng	x
7	Giấy chứng nhận hợp chuẩn	x
8	Giấy chứng nhận lưu hành tự do đối với trang thiết bị y tế nhập khẩu	x

PHỤ LỤC: BẢNG KÊ CHI TIẾT TRANG THIẾT BỊ Y TẾ

STT	TÊN TRANG THIẾT BỊ Y TẾ	CHỦNG LOẠI	MÃ SẢN PHẨM (Nếu có)	QUY CÁCH ĐÓNG GÓI (Nếu có)	TÊN CƠ SỞ SẢN XUẤT	ĐỊA CHỈ CƠ SỞ SẢN XUẤT	NƯỚC SẢN XUẤT
1	Khớp nối	Magic Angled Abutment	MAAH40115AB MAAH40215AB MAAH40315AB MAAH40415AB MAAH40123AB MAAH40223AB MAAH40323AB MAAH40423AB MAAH45115AB MAAH45215AB MAAH45315AB MAAH45415AB MAAH45123AB MAAH45223AB MAAH45323AB MAAH45423AB MAAH55115AB MAAH55215AB MAAH55315AB MAAH55415AB MAAH55123AB MAAH55223AB MAAH55323AB MAAH55423AB MAAH40115BB MAAH40215BB MAAH40315BB MAAH40415BB MAAH40123BB MAAH40223BB MAAH40323BB MAAH40423BB MAAH45115BB MAAH45215BB MAAH45315BB MAAH45415BB MAAH45123BB MAAH45223BB MAAH45323BB MAAH45423BB MAAH55115BB MAAH55215BB MAAH55315BB MAAH55415BB MAAH55123BB MAAH55223BB MAAH55323BB		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF

			MAAH55423BB MAAN40115B MAAN40215B MAAN40315B MAAN40415B MAAN40123B MAAN40223B MAAN40323B MAAN40423B MAAN45115B MAAN45215B MAAN45315B MAAN45415B MAAN45123B MAAN45223B MAAN45323B MAAN45423B MAAN55115B MAAN55215B MAAN55315B MAAN55415B MAAN55123B MAAN55223B MAAN55323B MAAN55423B			
2	Bộ khớp nối	Magic Angled Abutment SET	MAAH40115A MAAH40215A MAAH40315A MAAH40415A MAAH40123A MAAH40223A MAAH40323A MAAH40423A MAAH45115A MAAH45215A MAAH45315A MAAH45415A MAAH45123A MAAH45223A MAAH45323A MAAH45423A MAAH55115A MAAH55215A MAAH55315A MAAH55415A MAAH55123A MAAH55223A MAAH55323A MAAH55423A MAAH40115B MAAH40215B MAAH40315B MAAH40415B MAAH40123B	Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF

			MAAH40223B MAAH40323B MAAH40423B MAAH45115B MAAH45215B MAAH45315B MAAH45415B MAAH45123B MAAH45223B MAAH45323B MAAH45423B MAAH55115B MAAH55215B MAAH55315B MAAH55415B MAAH55123B MAAH55223B MAAH55323B MAAH55423B MAAN40115 MAAN40215 MAAN40315 MAAN40415 MAAN40123 MAAN40223 MAAN40323 MAAN40423 MAAN45115 MAAN45215 MAAN45315 MAAN45415 MAAN45123 MAAN45223 MAAN45323 MAAN45423 MAAN55115 MAAN55215 MAAN55315 MAAN55415 MAAN55123 MAAN55223 MAAN55323 MAAN55423			
3	Chân trụ răng	Magicare	451M4007 452M4007 453M4007 454M4007 455M4007 456M4007 457M4007 458M4007 459M4007 4510M4007 451M4009	Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF

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4	Chân trụ răng	Magicore 3 Series	401M3007 402M3007 403M3007 404M3007 405M3007 401M3009 402M3009 403M3009 404M3009 405M3009 401M3011 402M3011 403M3011 404M3011 405M3011 401M3013 402M3013 403M3013 404M3013 405M3013 401M3015 402M3015 403M3015 404M3015 405M3015 401M3507 402M3507 403M3507 404M3507 405M3507 401M3509 402M3509 403M3509 404M3509 405M3509 401M3511 402M3511 403M3511 404M3511 405M3511 401M3513 402M3513 403M3513 404M3513 405M3513 401M3515 402M3515 403M3515 404M3515 405M3515	Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF

5	Khớp nối	Magicore Solid Abutment	MA4502B MA4503B MA4504B MA4505B MA4506B MA5002B MA5003B MA5004B MA5005B MA5006B MA5502B MA5503B MA5504B MA5505B MA5506B MA6002B MA6003B MA6004B MA6005B MA6006B		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF
6	Bộ khớp nối	Link cylinder SET (Hexa)	MLH4510 MLH4520 MLH4530 MLH4531 MLH4540 MLH4541 MLH4542 MLH5010 MLH5020 MLH5030 MLH5031 MLH5040 MLH5041 MLH5042 MLH5510 MLH5520 MLH5530 MLH5531 MLH5540 MLH5541 MLH5542		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF
7	Bộ khớp nối	Link cylinder SET (Non-Hex)	MLN4510 MLN4520 MLN4530 MLN4531 MLN4540 MLN4541 MLN4542 MLN5010 MLN5020 MLN5030 MLN5031 MLN5040		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF

			MLN5041 MLN5042 MLN5510 MLN5520 MLN5530 MLN5531 MLN5540 MLN5541 MLN5542				
8	Vít vắn khớp nối	Abutment Screw	MPCS MPCSN		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF
9	Khớp nối	Link Cylinder (Hex)	MLH4510C MLH4520C MLH4530C MLH4531C MLH4540C MLH4541C MLH4542C MLH5010C MLH5020C MLH5030C MLH5031C MLH5040C MLH5041C MLH5042C MLH5510C MLH5520C MLH5530C MLH5531C MLH5540C MLH5541C MLH5542C		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF
10	Khớp nối	Link Cylinder (Non-Hex)	MLN4510C MLN4520C MLN4530C MLN4531C MLN4540C MLN4541C MLN4542C MLN5010C MLN5020C MLN5030C MLN5031C MLN5040C MLN5041C MLN5042C MLN5510C MLN5520C MLN5530C MLN5531C MLN5540C		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF

			MLN5541C MLN5542C				
11	Khớp nối	Magicore Link Cylinder	MLH402B MLH403B MLH404B MLH452B MLH453B MLH454B MLH552B MLH553B MLH554B MLN402B MLN403B MLN404B MLN452B MLN453B MLN454B MLN552B MLN553B MLN554B		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF
12	Bộ khớp nối	Magicore Link Cylinder SET	MLH402 MLH403 MLH404 MLH452 MLH453 MLH454 MLH552 MLH553 MLH554 MLN402 MLN403 MLN404 MLN452 MLN453 MLN454 MLN552 MLN553 MLN554		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF
13	Bộ khớp nối	Magicore Solid Abutment SET	MA4502 MA4503 MA4504 MA4505 MA4506 MA5002 MA5003 MA5004 MA5005 MA5006 MA5502 MA5503 MA5504		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF

			MA5505 MA5506 MA6002 MA6003 MA6004 MA6005 MA6006				
14	Vít ren	Closing Screw	HISC07 HISCY HISCB HISCG HISCP HISC25		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF
15	Khớp nối	MagiCore Customized Abutment	MC45H0510AB MC45H0610AB MC45H1010AB MC45H1210AB MC45H1410AB MC45H0520AB MC45H0620AB MC45H1020AB MC45H1220AB MC45H1420AB MC45N0510AB MC45N0610AB MC45N1010AB MC45N1210AB MC45N1410AB MC45N0520AB MC45N0620AB MC45N1020AB MC45N1220AB MC45N1420AB MC45H0510DB MC45H0610DB MC45H1010DB MC45H1210DB MC45H1410DB MC45H0520DB MC45H0620DB MC45H1020DB MC45H1220DB MC45H1420DB MC45N0510DB MC45N0610DB MC45N1010DB MC45N1210DB MC45N1410DB MC45N0520DB MC45N0620DB MC45N1020DB MC45N1220DB MC45N1420DB		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF

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MC55H1220D
MC55H1420D
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MC55N0610D

			MC55N1010D MC55N1210D MC55N1410D MC55N0520D MC55N0620D MC55N1020D MC55N1220D MC55N1420D				
16	Khớp nối	Burn out core cylinder	MPC45S MPC45ST MPC50S MPC55S MPC55ST MPC60S MPC45B MPC45BT MPC50B MPC55B MPC55BT MPC60B		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF
17	Bộ khớp nối	Burn out core cylinder SET	MPSR45S MPSR45ST MPSR50S MPSR55S MPSR55ST MPSR60S MPSR45B MPSR45BT MPSR50B MPSR55B MPSR55BT MPSR60B		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF
18	Nắp khớp nối	Burn out core cap	MPLP45S MPLP50S MPLP55S MPLP60S MPLP45B MPLP50B MPLP55B MPLP60B		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF
19	Nắp trụ lạnh thương	Magicore Abutment Cap	MA4002C MA4003C MA4004C MA4005C MA4006C MA4502C MA4503C MA4504C MA4505C		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF

			MA4506C MA5002C MA5003C MA5004C MA5005C MA5006C MA5502C MA5503C MA5504C MA5505C MA5506C MA6002C MA6003C MA6004C MA6005C MA6006C				
20	Nắp trụ lành thương	Healing Cap	MACS CAP4.5 MACS CAP5.0 MACS CAP5.5 MACS CAP6.0 MACS CAP6.5 MACS CAP7.0 MP CAP4.0 MP CAP4.5 MP CAP5.0 MP CAP5.5 MP CAP6.0 MP CAP6.5	Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF	
21	Khớp nối	Short Abutment	MMAH4502B MMAH4503B MMAH4504B MMAH4505B MMAH4506B MMAH5002B MMAH5003B MMAH5004B MMAH5005B MMAH5006B MMAH5502B MMAH5503B MMAH5504B MMAH5505B MMAH5506B MMAH6002B MMAH6003B MMAH6004B MMAH6005B MMAH6006B MMAN4502B MMAN4503B MMAN4504B MMAN4505B MMAN4506B	Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF	

			MMAN5002B MMAN5003B MMAN5004B MMAN5005B MMAN5006B MMAN5502B MMAN5503B MMAN5504B MMAN5505B MMAN5506B MMAN6002B MMAN6003B MMAN6004B MMAN6005B MMAN6006B MMAH4002B MMAH4003B MMAH4004B MMAH4005B MMAH4006B MMAN4002B MMAN4003B MMAN4004B MMAN4005B MMAN4006B			
22	Bộ khớp nối	Short Abutment SET	MMAH4502 MMAH4503 MMAH4504 MMAH4505 MMAH4506 MMAH5002 MMAH5003 MMAH5004 MMAH5005 MMAH5006 MMAH5502 MMAH5503 MMAH5504 MMAH5505 MMAH5506 MMAH6002 MMAH6003 MMAH6004 MMAH6005 MMAH6006 MMAN4502 MMAN4503 MMAN4504 MMAN4505 MMAN4506 MMAN5002 MMAN5003 MMAN5004 MMAN5005	Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF

			MMAN5006 MMAN5502 MMAN5503 MMAN5504 MMAN5505 MMAN5506 MMAN6002 MMAN6003 MMAN6004 MMAN6005 MMAN6006				
23	Khớp nối	Magicore Solid Abutment Narrow	MA4002B MA4003B MA4004B MA4005B MA4006B		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF
24	Khớp nối	Magic Abutment	MMPH4002B MMPH4003B MMPH4004B MMPH4005B MMPH4006B MMPH4502B MMPH4503B MMPH4504B MMPH4505B MMPH4506B MMPH5002B MMPH5003B MMPH5004B MMPH5005B MMPH5006B MMPH5502B MMPH5503B MMPH5504B MMPH5505B MMPH5506B MMPH6002B MMPH6003B MMPH6004B MMPH6005B MMPH6006B MMPH6502B MMPH6503B MMPH6504B MMPH6505B MMPH6506B MMPN4002B MMPN4003B MMPN4004B MMPN4005B MMPN4006B MMPN4502B MMPN4503B		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF

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25	Bộ khớp nối	Magicore Abutment SET	MA4002 MA4003 MA4004 MA4005 MA4006		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF
26	Bộ khớp nối	Magic Abutment SET	MMAH4002 MMAH4003 MMAH4004 MMAH4005 MMAH4006 MMAN4002 MMAN4003 MMAN4004 MMAN4005 MMAN4006 MMPH4002 MMPH4003 MMPH4004 MMPH4005 MMPH4006 MMPH4502 MMPH4503 MMPH4504 MMPH4505 MMPH4506 MMPH5002 MMPH5003 MMPH5004 MMPH5005 MMPH5006 MMPH5502 MMPH5503 MMPH5504 MMPH5505 MMPH5506 MMPH6002 MMPH6003 MMPH6004 MMPH6005 MMPH6006 MMPH6502 MMPH6503 MMPH6504 MMPH6505 MMPH6506 MMPN4002 MMPN4003 MMPN4004 MMPN4005 MMPN4006 MMPN4502 MMPN4503 MMPN4504 MMPN4505		Innobiosurg Co., Ltd., Korea	44-19, Techno 10-ro, Yuseong-gu, Daejeon, Korea	KOREA, REPUBLIC OF

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