

香港特別行政區政府
衛生署
香港灣仔皇后大道東 213 號
胡忠大廈 17 樓及 21 樓



THE GOVERNMENT OF THE HONG KONG
SPECIAL ADMINISTRATIVE REGION
DEPARTMENT OF HEALTH
WU CHUNG HOUSE, 17TH & 21ST FLOORS,
213 QUEEN'S ROAD EAST,
WANCHAI, HONG KONG

本署檔案 OUR REF: (94) in DHHQ/1010/7/2 Pt.3

電話 TEL: (852) 2961 8944

圖文傳真 FAX: (852) 2127 7329

23 May 2022

Dear Doctor/ Dentist,

**Attention to Transplanting of Regulated Products
under the Human Organ Transplant Ordinance (Cap. 465)**

We would like to draw your attention to the transplanting of regulated products under the Human Organ Transplant Ordinance (Cap. 465) (“the Ordinance”).

The Ordinance is to prohibit commercial dealings in human organs intended for transplanting, to restrict the transplanting of human organs between living persons and the transplanting of imported human organs, and for supplementary purposes connected with those matters. Part 7 (Section 7A to 7E) of the Ordinance provides that the Director of Health (“the Director”) may, on application, exempt certain commercial products made from human organs, i.e., regulated products, for transplant purposes from the application of the Ordinance, given that the product falls within the definition of regulated product and meets the criteria for exemption under the Ordinance.

Before using the regulated products for transplant purpose, registered medical practitioners and dentists need to ensure that the regulated products have been exempted by the Director. The medical practitioners and dentists are reminded to:

- check with the updated list of the exempted regulated products to ascertain whether the regulated products of interest have already been exempted;
- look for the exemption number issued by the Department of Health (“the DH”) on the outer package of the regulated products;
- keep a good utilisation record of the exempted regulated products to allow tracing individual recipients of a particular batch of the regulated products; and
- report any serious adverse event and serious adverse reaction to the DH.

As the approved regulated products are exempted from the application of Section 6 of

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the Ordinance (Information about transplant operations), for transplants using exempted regulated products, the medical practitioners do not need to supply to the Human Organ Transplant Board the information as specified in the prescribed Form 2 of the Human Organ Transplant Regulation (Cap. 465A). In addition, the medical practitioners and dentists do not need to submit the DH Return Form on the transplant of the exempted regulated products to the DH.

The list of the exempted regulated products as at 23 May 2022 is enclosed herewith for your reference. Information on the exemption of the regulated products under the Ordinance, including the updated list of the exempted regulated products, is available at https://www.dh.gov.hk/english/useful/hot_exemption.html (accessible via the QR code below). Should you have any doubts on the exemption status of the regulated products or any other questions on the exemption of regulated products, please feel free to contact us at -

Address: Health Technology and Advisory Division
Department of Health
21/F, Wu Chung House
213 Queen's Road East,
Wanchai, Hong Kong

Tel: (852) 2961 8944
Fax: (852) 2127 7329
Email: hot_rpe@dh.gov.hk



Thank you for your attention.

Yours faithfully,

A handwritten signature in black ink, appearing to read 'Raymond Leung', positioned above the printed name.

(Dr Raymond LEUNG)
for Director of Health

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List of currently exempted products

現時獲豁免的受規管產品

	Name (and other identifiers) of exempted regulated product 產品名稱 (及其他識別資料)	Exemption no. 豁免編號 (HK-RPEX No.)	Name of importer, local distributor and/or seller 進口商、本地分銷商及/或銷售商的名稱	Name and country of manufacturer 製造商的名稱及所在國家	Validity of exemption (Both dates inclusive) 豁免的有效期 (首末兩天包括在內)		Remarks 備註
					From 由	To 至	
1	GRAFTON® DBM Gel:						
	T41110INT GRAFTON® DBM Gel, 0.5cc T41120INT GRAFTON® DBM Gel, 1cc T41130INT GRAFTON® DBM Gel, 5cc T41150INT GRAFTON® DBM Gel, 10cc	2012B-0001-1 2012B-0001-2 2012B-0001-3 2012B-0001-4	Medtronic Hong Kong Medical Limited	Medtronic Sofamor Danek USA, Inc., USA	13/06/2012	12/06/2022	
2	GRAFTON® DBM Flex:						
	T42090INT GRAFTON® DBM Flex, 1.5cm x 1.5cm T42100INT GRAFTON® DBM Flex, 2.5cm x 10cm T42110INT GRAFTON® DBM Flex, 2.5cm x 5cm T42150INT GRAFTON® DBM Flex, 5cm x 5cm	2012B-0002-1 2012B-0002-2 2012B-0002-3 2012B-0002-4	Medtronic Hong Kong Medical Limited	Medtronic Sofamor Danek USA, Inc., USA	13/06/2012	12/06/2022	

	Name (and other identifiers) of exempted regulated product 產品名稱 (及其他識別資料)	Exemption no. 豁免編號 (HK-RPEX No.)	Name of importer, local distributor and/or seller 進口商、本地分銷商 及/或銷售商的名稱	Name and country of manufacturer 製造商的名稱及 所在國家	Validity of exemption (Both dates inclusive)		Remarks 備註
					豁免的有效期 (首末兩天包括在內)		
					From 由	To 至	
3	GRAFTON® DBM Putty:						
	T43204INT GRAFTON® DBM Putty, 0.25cc syringe T43205INT GRAFTON® DBM Putty, 0.5cc syringe T43101INT GRAFTON® DBM Putty, 0.5 cc jar T43102INT GRAFTON® DBM Putty, 1cc jar T43103INT GRAFTON® DBM Putty, 2.5cc jar T43105INT GRAFTON® DBM Putty, 5cc jar T43110INT GRAFTON® DBM Putty, 10cc jar	2012B-0004-1 2012B-0004-2 2012B-0004-3 2012B-0004-4 2012B-0004-5 2012B-0004-6 2012B-0004-7	Medtronic Hong Kong Medical Limited	Medtronic Sofamor Danek USA, Inc., USA	13/06/2012	12/06/2022	
4	GRAFTON® DBM Matrix/ Matrix Strips:						
	T42210INT GRAFTON® DBM Matrix, 2.5cm x 5cm (2 each) T42200INT GRAFTON® DBM Matrix, 2.5cm x 10cm (2 each) T42275INT GRAFTON® DBM Matrix Strips, 8mm x 1cm x 10cm (2 each) T42280INT GRAFTON® DBM Matrix Strips, 8mm x 1cm x 20cm (2 each)	2012B-0005-1 2012B-0005-2 2012B-0005-3 2012B-0005-4	Medtronic Hong Kong Medical Limited	Medtronic Sofamor Danek USA, Inc., USA	13/06/2012	12/06/2022	
5	GRAFTON® DBM Matrix Plugs:						
	T42308INT GRAFTON® DBM Matrix Plugs, 8mm x 10mm	2012B-0006-1	Medtronic Hong Kong Medical Limited	Medtronic Sofamor Danek USA, Inc., USA	13/06/2012	12/06/2022	

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					豁免的有效期 (首末兩天包括在內)		
					From 由	To 至	
6	GRAFTON® DBM Crunch:						
	T44105INT GRAFTON® DBM Crunch, 5cc T44115INT GRAFTON® DBM Crunch, 15cc	2012B-0007-1 2012B-0007-2	Medtronic Hong Kong Medical Limited	Medtronic Sofamor Danek USA, Inc., USA	13/06/2012	12/06/2022	
7	GRAFTON® DBM Orthoblend:						
	T44125INT GRAFTON® DBM Orthoblend, 5cc – Large defect T44135INT GRAFTON® DBM Orthoblend, 15cc – Large defect T44145INT GRAFTON® DBM Orthoblend, 5cc – Small defect T44150INT GRAFTON® DBM Orthoblend, 10cc – Small defect	2012B-0008-1 2012B-0008-2 2012B-0008-3 2012B-0008-4	Medtronic Hong Kong Medical Limited	Medtronic Sofamor Danek USA, Inc., USA	13/06/2012	12/06/2022	
8	GRAFTON PLUS® DBM Paste:						
	T45001INT GRAFTON PLUS® DBM Paste, 1cc T45005INT GRAFTON PLUS® DBM Paste, 5cc T45010INT GRAFTON PLUS® DBM Paste, 10cc	2012B-0009-1 2012B-0009-2 2012B-0009-3	Medtronic Hong Kong Medical Limited	Medtronic Sofamor Danek USA, Inc., USA	13/06/2012	12/06/2022	

	Name (and other identifiers) of exempted regulated product 產品名稱 (及其他識別資料)	Exemption no. 豁免編號 (HK-RPEX No.)	Name of importer, local distributor and/or seller 進口商、本地分銷商及/或銷售商的名稱	Name and country of manufacturer 製造商的名稱及所在國家	Validity of exemption (Both dates inclusive) 豁免的有效期 (首末兩天包括在內)		Remarks 備註
					From 由	To 至	
9	SureOss™-FDBA Powder:						
	SOP025 SureOss™-FDBA Powder, 0.25cc SOP050 SureOss™-FDBA Powder, 0.5cc SOP100 SureOss™-FDBA Powder, 1cc	2012E-0010-1 2012E-0010-2 2012E-0010-3	Osstem Hong Kong Limited	HansBiomed Corp., Republic of Korea	09/10/2012	08/10/2022	
10	SureOss™-FDBA Chip:						
	SOC025 SureOss™-FDBA Chip, 0.25cc SOC050 SureOss™-FDBA Chip, 0.5cc SOC100 SureOss™-FDBA Chip, 1cc	2012E-0011-1 2012E-0011-2 2012E-0011-3	Osstem Hong Kong Limited	HansBiomed Corp., Republic of Korea	09/10/2012	08/10/2022	
11	OraGRAFT® Cancellous Bone Particulate:						
	O CAN-0.5A OraGRAFT® Cancellous Bone Particulate, 0.5cc (250-1000 micron) O CAN-1.0A OraGRAFT® Cancellous Bone Particulate, 1cc (250-1000 micron) O CAN-2.0A OraGRAFT® Cancellous Bone Particulate, 2cc (250-1000 micron) O CAN-0.5B OraGRAFT® Cancellous Bone Particulate, 0.5cc (1-2 mm) O CAN-1.0B OraGRAFT® Cancellous Bone Particulate, 1cc (1-2 mm) O CAN-2.0B OraGRAFT® Cancellous Bone Particulate, 2cc (1-2 mm)	2012F-0014-1 2012F-0014-2 2012F-0014-3 2012F-0014-4 2012F-0014-5 2012F-0014-6	Forever Green Dental Products Limited	LifeNet Health, United States of America	09/10/2012	08/10/2022	

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					豁免的有效期 (首末兩天包括在內)		
					From 由	To 至	
12	OraGRAFT® Cancellous Bone Cubes:						
	CANCUBE1 OraGRAFT® Cancellous Bone Cubes, 10x10x10mm	2012F-0015-1	Forever Green Dental Products Limited	LifeNet Health, United States of America	09/10/2012	08/10/2022	
	CCUBE-01 OraGRAFT® Cancellous Bone Cubes, 15x15x15mm	2012F-0015-2					
	CCUBE-02 OraGRAFT® Cancellous Bone Cubes, 15x15x8mm	2012F-0015-3					
	CCUBE-03 OraGRAFT® Cancellous Bone Cubes, 15x30x8mm	2012F-0015-4					
13	OraGRAFT® Demineralized Ground Cortical Bone:						
	DGC 1/20 OraGRAFT® Demineralized Ground Cortical Bone, 0.25cc (250-1000 micron)	2012F-0016-1	Forever Green Dental Products Limited	LifeNet Health, United States of America	09/10/2012	08/10/2022	
	DGC 1/10 OraGRAFT® Demineralized Ground Cortical Bone, 0.5cc (250-1000 micron)	2012F-0016-2					
	DGC 1/8 OraGRAFT® Demineralized Ground Cortical Bone, 0.7cc (250-1000 micron)	2012F-0016-3					
	DGC 1/4 OraGRAFT® Demineralized Ground Cortical Bone, 1.2cc (250-1000 micron)	2012F-0016-4					
	DGC OraGRAFT® Demineralized Ground Cortical Bone, 2.5cc (250-1000 micron)	2012F-0016-5					
	DGC 5 OraGRAFT® Demineralized Ground Cortical Bone, 5.0cc (1-4mm)	2012F-0016-6					

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					豁免的有效期 (首末兩天包括在內)		
					From 由	To 至	
14	OraGRAFT® Mineralized Ground Cortical Bone:						
	GC 1/20 OraGRAFT® Mineralized Ground Cortical Bone, 0.25cc (250-1000 micron)	2012F-0017-1	Forever Green Dental Products Limited	LifeNet Health, United States of America	09/10/2012	08/10/2022	
	GC 1/10 OraGRAFT® Mineralized Ground Cortical Bone, 0.5cc (250-1000 micron)	2012F-0017-2					
	GC 1/8 OraGRAFT® Mineralized Ground Cortical Bone, 0.7cc (250-1000 micron)	2012F-0017-3					
	GC 1/4 OraGRAFT® Mineralized Ground Cortical Bone, 1.2cc (250-1000 micron)	2012F-0017-4					
	GC OraGRAFT® Mineralized Ground Cortical Bone, 2.5cc (250-1000 micron)	2012F-0017-5					
15	OraGRAFT® Cortical/Cancellous Mix						
	C/CMix-0.5 OraGRAFT® Cortical/Cancellous Mix, 0.5cc	2014F-0013-1	Forever Green Dental Products Limited	LifeNet Health, United States of America	07/11/2014	08/10/2022	
	C/CMix-1.0 OraGRAFT® Cortical/Cancellous Mix, 1cc	2014F-0013-2					
	C/CMix-2.0 OraGRAFT® Cortical/Cancellous Mix, 2cc	2014F-0013-3					

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					豁免的有效期 (首末兩天包括在內)		
					From 由	To 至	
16	Puros® Cancellous Particulate Allograft						
	68210 Puros® Cancellous Particulate Allograft, 250-1000 microns, 0.5cc	2017H-0005-1	Healthcare Dental Limited	RTI Biologics, Inc., USA	15/09/2017	14/09/2022	
	68211 Puros® Cancellous Particulate Allograft, 250-1000 microns, 1cc	2017H-0005-2					
	68209 Puros® Cancellous Particulate Allograft, 250-1000 microns, 2cc	2017H-0005-3					
	68212 Puros® Cancellous Particulate Allograft, 1000-2000 microns, 0.5cc	2017H-0005-4					
	68213 Puros® Cancellous Particulate Allograft, 1000-2000 microns, 1cc	2017H-0005-5					
	68214 Puros® Cancellous Particulate Allograft, 1000-2000 microns, 2cc	2017H-0005-6					

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					豁免的有效期 (首末兩天包括在內)		
					From 由	To 至	
17	Puros® Cortico-Cancellous Particulate Allograft						
	68800 Puros® Cortico-Cancellous Particulate Allograft, 250-1000 microns, 0.5cc	2017H-0006-1	Healthcare Dental Limited	RTI Biologics, Inc., USA	15/09/2017	14/09/2022	
	68801 Puros® Cortico-Cancellous Particulate Allograft, 250-1000 microns, 1cc	2017H-0006-2					
	68802 Puros® Cortico-Cancellous Particulate Allograft, 250-1000 microns, 2cc	2017H-0006-3					
	68803 Puros® Cortico-Cancellous Particulate Allograft, 1000-2000 microns, 0.5cc	2017H-0006-4					
	68804 Puros® Cortico-Cancellous Particulate Allograft, 1000-2000 microns, 1cc	2017H-0006-5					
	68805 Puros® Cortico-Cancellous Particulate Allograft, 1000-2000 microns, 2cc	2017H-0006-6					

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					豁免的有效期 (首末兩天包括在內)		
					From 由	To 至	
18	Puros® Cortical Particulate Allograft						
	68271 Puros® Cortical Particulate Allograft, 250-1000 microns, 0.5cc	2017H-0007-1	Healthcare Dental Limited	RTI Biologics, Inc., USA	15/09/2017	14/09/2022	
	68272 Puros® Cortical Particulate Allograft, 250-1000 microns, 1cc	2017H-0007-2					
	68273 Puros® Cortical Particulate Allograft, 250-1000 microns, 2cc	2017H-0007-3					
	68274 Puros® Cortical Particulate Allograft, 1000-2000 microns, 0.5cc	2017H-0007-4					
	68275 Puros® Cortical Particulate Allograft, 1000-2000 microns, 1cc	2017H-0007-5					
	68276 Puros® Cortical Particulate Allograft, 1000-2000 microns, 2cc	2017H-0007-6					

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19	CGDBM Allomix						
	CART0500 CGDBM Allomix, 5cc CART1000 CGDBM Allomix, 10cc	2018Q-0004-1 2018Q-0004-2	Kinwood Healthcare Limited	CG Bio Co., Ltd., Republic of Korea	18/07/2018	17/07/2023	
20	OsteOss™ Powder						
	CCP025 OsteOss™ Powder, 0.25cc CCP050 OsteOss™ Powder, 0.5cc CCP100 OsteOss™ Powder, 1cc	2014J-0003-1 2014J-0003-2 2014J-0003-3	Asia Implant Support and Services Limited	HansBiomed Corp., Republic of Korea	14/08/2019	13/08/2024	
21	OsteOss™ Chip						
	CCC025 OsteOss™ Chip, 0.25cc CCC050 OsteOss™ Chip, 0.5cc CCC100 OsteOss™ Chip, 1cc	2014J-0004-1 2014J-0004-2 2014J-0004-3	Asia Implant Support and Services Limited	HansBiomed Corp., Republic of Korea	14/08/2019	13/08/2024	
22	SureOss™-FDBA Powder						
	SOP025 SureOss™-FDBA Powder, 0.25cc SOP050 SureOss™-FDBA Powder, 0.5cc SOP100 SureOss™-FDBA Powder, 1cc	2014J-0009-1 2014J-0009-2 2014J-0009-3	Asia Implant Support and Services Limited	HansBiomed Corp., Republic of Korea	14/08/2019	13/08/2024	

	Name (and other identifiers) of exempted regulated product 產品名稱 (及其他識別資料)	Exemption no. 豁免編號 (HK-RPEX No.)	Name of importer, local distributor and/or seller 進口商、本地分銷商 及/或銷售商的名稱	Name and country of manufacturer 製造商的名稱及 所在國家	Validity of exemption (Both dates inclusive)		Remarks 備註
					豁免的有效期 (首末兩天包括在內)		
					From 由	To 至	
23	SureOss™-FDBA Chip						
	SOC025 SureOss™-FDBA Chip, 0.25cc SOC050 SureOss™-FDBA Chip, 0.5cc SOC100 SureOss™-FDBA Chip, 1cc	2014J-0010-1 2014J-0010-2 2014J-0010-3	Asia Implant Support and Services Limited	HansBiomed Corp., Republic of Korea	14/08/2019	13/08/2024	
24	OrACELL Decellularized Dermis						
	OCELL100 OrACELL Decellularized Dermis 1.5 X 2 cm (thickness: 0.76-1.25mm) OCELL101 OrACELL Decellularized Dermis 2 X 4 cm (thickness: 0.76-1.25mm) OCELL150 OrACELL Decellularized Dermis 1 X 1 cm (thickness: 0.76-1.25mm) OCELL151 OrACELL Decellularized Dermis 1 X 4 cm (thickness: 0.76-1.25mm) OCELL200 OrACELL Decellularized Dermis 1.5 X 2 cm (thickness: 1.26-1.75mm) OCELL201 OrACELL Decellularized Dermis 2 X 4 cm (thickness: 1.26-1.75mm) OCELL250 OrACELL Decellularized Dermis 1 X 1 cm (thickness: 1.26-1.75mm) OCELL251 OrACELL Decellularized Dermis 1 X 4 cm (thickness: 1.26-1.75mm)	2021F-0001-1 2021F-0001-2 2021F-0001-3 2021F-0001-4 2021F-0001-5 2021F-0001-6 2021F-0001-7 2021F-0001-8	Forever Green Dental Products Limited	LifeNet Health, United States of America	16/09/2021	15/09/2026	

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					From 由	To 至	
25	DBX® Demineralized Bone Matrix Putty						
	038005 DBX, Putty, 0.5cc 038010 DBX, Putty, 1cc 038025 DBX, Putty, 2.5cc 038050 DBX, Putty, 5cc 038100 DBX, Putty, 10cc	2011A-0001-1 2011A-0001-2 2011A-0001-3 2011A-0001-4 2011A-0001-5	Johnson & Johnson (Hong Kong) Ltd.	MTF Musculoskeletal Transplant Foundation, USA	10/11/2021	9/11/2026	
26	Allomatrix® Injectable Putty						
	8600-0050 Allomatrix® Injectable Putty, 0.5cc 8600-0100 Allomatrix® Injectable Putty, 1cc 8600-0500 Allomatrix® Injectable Putty, 5cc 8600-1000 Allomatrix® Injectable Putty, 10cc 8600-2000 Allomatrix® Injectable Putty, 20cc	2021U-0002-1 2021U-0002-2 2021U-0002-3 2021U-0002-4 2021U-0002-5	Stryker China Limited	Wright Medical Technology, Inc., USA	24/11/2021	23/11/2026	
27	MinerOss® Cortical & Cancellous Chips:						
	T00961INT MinerOss® Cortical & Cancellous Chips, 0.5cc T00962INT MinerOss® Cortical & Cancellous Chips, 1.0cc T00963INT MinerOss® Cortical & Cancellous Chips, 2.5cc	2016C-0001-1 2016C-0001-2 2016C-0001-3	Henry Schein Hong Kong Limited	Medtronic Sofamor Danek USA, Inc.	07/03/2022	06/03/2027	