


**Certificate of Accreditation, Designation, Authorisation or Licence of an Importing Tissue Establishment**
**1. Importing Tissue Establishment (ITE) Details**

1.1	Name of ITE	BioHorizons UK	
1.2	EU Tissue Establishment Compendium Code	GB011008	
1.3	ITE Address and postal address <i>(if different)</i>	1st floor Suite, Richmond House, Oldbury Road, Bracknell, Berkshire, RG12 8TQ, Great Britain	
1.4	Site of reception of imports <i>(if different from the above address)</i>		
1.5	Name of accreditation, designation, authorisation or licence holder	BioHorizons Implant Systems Inc.	
1.6	Address of accreditation, designation, authorisation or licence holder	2300 Riverchase Center, Birmingham, Alabama, 35244, United States	
1.7	Telephone number of accreditation, designation, authorisation or licence holder <i>(optional)</i>		
1.8	Email address of accreditation, designation, authorisation or licence holder <i>(optional)</i>		
1.9	URL of ITE website	<a href="http://www.biohorizons.com/">http://www.biohorizons.com/</a>	

2. Scope of Activities								
2.1	Type of Tissues and Cells	Activities in third countries					Import Accreditation, Designation, Authorisation or Licence Status	
	<i>(list below using categories of tissues and cells listed in the EU Tissue Establishment Compendium adding rows as necessary)</i>	Donation	Procurement	Testing	Preservation	Processing		Storage
	Membrane; Pericardium	SC	SC	SC		SC	3CS	G
	Musculoskeletal, Bone; Acellular Bone	SC	SC	SC		SC	3CS	G
	Musculoskeletal, Bone; Cancellous Bone Particles	SC	SC	SC		SC	3CS	G
	Musculoskeletal, Bone; DBM	SC	SC	SC		SC	3CS	G
	Musculoskeletal, Bone; DBM Putty	SC	SC	SC		SC	3CS	G
	Skin	SC	SC	SC		SC	3CS	G
		3CS - Third country supplier					G- Granted	
		SC - Sub-contractor of third country supplier					S-Suspended R-Revoked C- Cessation	
2.2	One-off imports	<input type="checkbox"/>						
2.3	Product name(s) of imported tissues and cells	Mem-Lok Pericardium MinerOss Block MinerOss Grafton (DBM) Grafton (DBM Putty) AlloDerm AlloDerm GBR						
2.4	Any conditions placed on the import or clarifying remarks	The HTA does not licence preservation as a standalone activity. The assessment of this activity is included through a licence for processing and/or storage.						
2.5	Third country or countries of procurement <i>(per tissue and cell import)</i>	United States of America						
2.6	Third country or countries in which other activities take place <i>(if different)</i>							
2.7	Name and country of third country supplier(s) <i>(per tissue and cell import)</i>	BioHorizons Implant Systems, Inc. United States of America						

2.8	EU Member States in which imported tissues and cells will be distributed ( <i>if known</i> )	
<b>3. Competent Authority (CA) Accreditation, Designation, Authorisation or Licence</b>		
3.1	National accreditation, designation, authorisation or licence number	11008
3.2	Legal basis of accreditation, designation, authorisation or licence	Licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)
3.3	Date of expiry of accreditation, designation, authorisation or licence ( <i>if any</i> )	Remains in force until revoked.
3.4	First accreditation, designation, authorisation or licence as ITE or renewal	First time <input type="checkbox"/> Renewal <input checked="" type="checkbox"/>
3.5	Additional remarks	
3.6	Name of CA	Human Tissue Authority
3.7	Name of CA officer	Christopher Birkett
3.8	Signature of CA officer ( <i>electronic or otherwise</i> )	
3.9	Date of accreditation, designation, authorisation or licence	June 2018
3.10	CA Stamp	Issued electronically