

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)</b> <i>(See reverse side for instructions)</i>	<b>1. REGISTRATION NUMBER</b> (Field Establishment Identifier)  FEI: 3003739398	<b>2. REASON FOR SUBMISSION</b> a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY 1 VALIDATED BY FDA:28-JAN-2009 DISTRICT: Int'l Operations Group PRINTED BY FDA:12-NOV-2009
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION															
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps	11. HCT/PS DESCRIBED IN 21 CFR 1271.10	12. HCT/PS REGULATED AS MEDICAL DEVICES	13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)	Establishment Functions										
a. BLOOD FDA 2830 NO. _____  b. DEVICES FDA 2891 NO. _____  c. DRUG FDA 2656 NO. _____	Types of HCT / Ps					Recover	Screen	Test	Package	Process	Store	Label	Distribute			
<b>4. PHYSICAL LOCATION</b> <i>(Include legal name, number and street, city, state, country, and post office code)</i> Cryos International - Denmark, ApS Vesterbro Torv 1-3, 5th floor Århus, 8000C Denmark  a. PHONE +45 86 76 06 99 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone  b. Cartilage  c. Cornea  d. Dura Mater  e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous  f. Fascia															
<b>5. ENTER CORRECTIONS TO ITEM 4</b>	g. Heart Valve  h. Ligament  i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous  j. Pericardium  k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic  l. Sclera  m. Semen <input type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous															
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> Cryos International Denmark, ApS Attn: Ole Schou Vesterbro Torv 1-3, 5th floor Aarhus, 8000C Denmark  a. PHONE +4586760699 EXT _____	n. Skin  o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic  p. Tendon  q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic  r. Vascular Graft															
<b>7. ENTER CORRECTIONS TO ITEM 6</b> b. PHONE _____	s.  t.  u.  v.															
<b>8. U.S. AGENT</b> Claus B. Rodgaard Cryos International New York, LLC 90 Maiden Lane, suite 302, New York, New York 10038  a. E-MAIL ny@cryosinternational.com 2124305950																
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Ole Schou b. E-MAIL dk@cryosinternational.com c. TITLE CEO d. DATE _____																

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PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

**ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,  
AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)**

*(See reverse side for instructions)*

**1. REGISTRATION NUMBER**

(Field Establishment Identifier)

FEI: 3003739398

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**ADDITIONAL INFORMATION:**

This submission is due to our new address.

Kind regards  
Thomas Ebbesen

**Proprietary Name(s):**