DEPARTMENT OF HEALTH AND HUMAN SERVICES
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

2. REASON FOR SUBMISSION
a. [ ] INITIAL REGISTRATION / LISTING
b. [X] ANNUAL REGISTRATION / LISTING
c. [ ] CHANGE IN INFORMATION
d. [ ] INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:21-NOV-2011
DISTRICT: Int'l Operations Group
PRINTED BY FDA:23-NOV-2011

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. _____

b. DEVICES FDA 2891 NO. _____

c. DRUG FDA 2656 NO. _____

4. PHYSICAL LOCATION *(Include legal name, number and street, city, state, country, and post office code)*

Cryos International - Denmark, ApS
Vesterbro Torv 1-3, 5th floor
Århus, 8000C
Denmark

a. PHONE +45 86 76 06 99 EXT

b. [ ] SATELLITE RECOVERY ESTABLISHMENT
(MANUFACTURING ESTABLISHMENT FEI NO._____

c. [ ] TESTING FOR MICRO-ORGANISMS ONLY

5. ENTER CORRECTIONS TO ITEM 4

6. MAILING ADDRESS OF REPORTING OFFICIAL *(Include institution name if applicable, number and street, city, state, country, and post office code)*

Cryos International Denmark, ApS
Attn: Ole Schou
Vesterbro Torv 1-3, 5th floor
Aarhus, 8000C
Denmark

a. PHONE +4586760699 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT Ty Kalisky

Cryos International - New York, LLC
90 Maiden Lane, suite 302, New York, New York 10038

a. E-MAIL ny@cryosinternational.com 2124305950

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Ole Schou

b. E-MAIL dk@cryosinternational.com

c. TITLE CEO d. DATE 20-NOV-2011

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	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)
a. Bone												
b. Cartilage												
c. Cornea												
d. Dura Mater												
e. Embryo [ ] SIP [X] Directed [ ] Anonymous						X		X	X			
f. Fascia												
g. Heart Valve												
h. Ligament												
i. Oocyte [ ] SIP [X] Directed [ ] Anonymous						X		X	X			
j. Pericardium												
k. Peripheral Blood Stem Cells [ ] Autologous [ ] Family Related [ ] Allogeneic												
l. Sclera												
m. Semen [ ] SIP [X] Directed [X] Anonymous	X	X	X	X	X	X	X	X	X			
n. Skin												
o. Somatic Cell Therapy Products [ ] Autologous [ ] Family Related [ ] Allogeneic												
p. Tendon												
q. Umbilical Cord Blood Stem Cells [ ] Autologous [ ] Family Related [ ] Allogeneic												
r. Vascular Graft												
s.												
t.												
u.												
v.												