TGA Therapeutic Goods Administration

Commonwealth Department of Health and Family Services

Therapeutic Devices Application

(Australian Register of Therapeutic Goods)

Use this form if you are applying for:

- Registration of Therapeutic Device(s)
- Listing of Therapeutic Device(s)
- Addition to either a Registration or Listing of a Therapeutic Device
- Variation to either a Registration or Listing of a Therapeutic Device
- Transfer of a device between the listed and registered categories

May 1998

It is the sponsor's responsibility to ensure that this form is accompanied by adequate data for evaluation (Registrable Devices) or all relevant documentation (Listable Devices) and includes the appropriate application fee.

INCOMPLETE APPLICATIONS WILL BE REJECTED.

4831.

1950 (9805)

Sponsor details *(all applicants to complete)*

1 **Sponsor's business and trading name** *(refer note opposite)*

EBOS HEALTH + SCIENCE PTY LTD

2 **Sponsor's address**

PO BOX 386
ALEXANDRIA NSW 2015

3 **Has an *"Enterprise Details"* form previously been submitted:** *(refer note opposite)*

(i) for this business? **Yes** ☑ **No** ☐

If **Yes**, give the Enterprise I.D. code: 144455

If **No**, please complete an *"Enterprise Details"* form and submit it with this application.

(ii) for the authorised person? **Yes** ☑ **No** ☐

If **No**, please complete an *"Enterprise Details"* form, Section D, and submit it with this application.

4 **Authorised Person's/ Authorised Agent's for this application**

JOHN GREEN

5 **Authorised Person's/ Authorised Agent's telephone number**

(02) 96996488 **Facsimile number** (02) 96984535

Agent's name

Agent's address

6 Declaration *(all applicants to complete)*

Sponsors should note the *"Therapeutic Goods Act 1989"* provides penalties for making statements that are false or misleading in connection with an application for registration or listing of therapeutic goods.

I declare that the information given is current and correct.

Signature of authorised person *(refer note opposite)*

Date 28/9/00

Name *(please print)* JOHN GREEN

Your position/title/office in relation to sponsor AUSTRALIAN MANAGER

Commercial - in - Confidence

7 **Is this device for export only?** Yes ☐ No ☑

8 **I am applying for** *(refer note opposite)*

- Registration of Therapeutic Device(s) ☐
- Listing of Therapeutic Device(s) ☑
- Addition of product(s) to an existing Registration ☐ — Specify AUSTR number
- Addition of product(s) to an existing Lisitng ☐ — Specify AUSTL number
- Variation to existing Registration/Listing ☐ — Specify AUSTL/R number
- ARTG transfer ☐ — Specify AUSTL/R number

Variation details ***(only applicants varying details of a registration or listing to complete)***

9 **Category of change**
(give a brief description)
(refer note opposite)

10 **Application fee**
(refer note opposite)

A $300.00

Commercial - in - Confidence

Manufacturer details - release for supply

11 **Manufacturer's name** OSTEOIMPLANT TECHNOLOGY INC

12 **TGA Licence number** *(Aust manufacturers only)* *(refer note opposite)* | **Has licence been applied for?** Yes ☐ No ☐

13 **Manufacturer's Enterprise I.D.** *(if known)* 32083 TLI

14 **Manufacturer's site address** *(refer note opposite)* 11201 PEPPER ROAD
HUNT VALLEY MARYLAND 21031 USA

15 **Manufacturer's postal address** *(if different to above)*

16 **Step(s) in manufacture** *(refer note opposite)* FULL

If 'FULL' go to question **22**

Other Key Step Manufacturers *(refer note opposite)*

17 **Manufacturer's name** *(refer note opposite)*

18 **Manufacturer's Enterprise I.D.** *(if known)*

19 **TGA Licence number** *(Aust manufacturers only)* | **Has licence been applied for?** Yes ☐ No ☐

20 **Manufacturer's site address**

21 **Step(s) in manufacture**

Overseas manufacturer - Quality Systems/GMP Certification
(registration and listing applicants to complete)

22 **Do the goods appear in the list opposite?**
(refer note opposite)

Yes ☑ **No** ☐ — *Go to question* **25**

If **Yes**, has evidence of quality systems/GMP certification for **each** manufacturer previously been accepted by the TGA?

Manufacturer 1
Yes ☐ No ☑

Manufacturer 2
Yes ☐ No ☐

Evidence must be no more than 5 years old and valid for at least 6 months at the time of applilcation

If **No**, attach evidence of quality systems certification *(refer notes opposite)*

23 **If evidence unavailable/unacceptable, do you agree to pay the costs of inspection by Australian TGA Auditor if deemed necessary by the Secretary?**

Yes ☐ No ☑

If **No**, attach a separate sheet giving reasons.

24 **Has/have the overseas manufacturer(s) agreed to such an inspection?**

Yes ☐ No ☐

If **No**, attach a separate sheet giving reasons.

Compliance with Therapeutic Goods Orders or prescribed quality and safety criteria *(registration and listing applicants to complete)*

25 **Do the goods appear in the list opposite?** *(refer note opposite)*

Yes ☐ No ☐

If **Yes**, you must have available a current test certificate demonstrating compliance with each requirement of the relevant standard. Test certificates must be less than 2 years old.

Note: 1. For condoms and contraceptive diaphragms the test certificate must be from an independent laboratory and relate to a batch to be supplied in Australia and be submitted with the application.
2. For non-sterile bandages and dressings where the manufacturer does not have a certified quality system/GMP – a Site Information File together with a microbial count certificate less than 6 months old for the first batch to be supplied in Australia, is required with the application.
Test certificates are required to be submitted for the next five batches of product to be supplied in Australia, prior to these batches being supplied.

Electrical Safety

26 **Is the device electrically powered?** **Yes** ☐ **No** ☑

Any electromedical device which is the subject of this application must provide documentary evidence in the form of a technical dossier which demonstrates compliance with the appropriate requirements below:

Australia

☐ AS 3200.1 – 1990 – Approval and test specification – Medical electrical equipment – Part 1 – General requirements for safety

☐ AS 3551 – 1996 – Technical management programs for medical devices (applicable clauses)

☐ Certificate of Approval number _____ issued by _____ of _____ (State) on _____ (Date)

☐ Certificate of Suitability number _____ issued by _____ of _____ (State) on _____ (Date)

Overseas

☐ IEC 601.1 – 1988 – Medical electrical equipment – Part 1 – General requirements for safety

OR Equivalent

☐ EN 60601.1 Europe

☐ BS 5724 United Kingdom

☐ UL 2601 United States

☐ CSA C22.26 – 601 Canada

☐ Certificate of compliance with IECEE-CB Scheme

Electromagnetic Compatibility

☐ AS/NZS 3200.1.2 – 1995 – Approval and test specification – General requirements for safety – Collateral Standard: – Electromagnetic compatibility – requirements and tests or AS/NZS 3200 part 2 standards applicable to specific items of equipment

Foreign approvals for Registrable Devices

27 **Has the product received prior approval from any other regulatory agency?** **Yes** ☑ **No** ☐

If **Yes**, indicate the type of prior approval
(Please attach separate evidence for each product)

US FDA Approval ☑	Pre Market Approval – PMA ☐	Date	
	Supplementary Pre-Market Approval – SPMA ☐	Date	
	Investigation Device Exemption – IDE ☐	Date	
	EC Design Examination Certificate ☐	Date	
	EC Type Examination Certificate ☐	Date	
	EC Quality Systems/GMP Certificate ☑		

Certification Agency: EUROPEAN — Approval date: 2 Mar 99

Type of Certificate *(refer note opposite)*: CE — Expiry date:

Regulatory record *(registration and listing applicants to complete)*
(refer note opposite)

28 **Have any of the therapeutic devices included in this application been refused registration in another country or are subject to:**

- any bans from sale or supply, product recall or product correction? **or**
- investigation in relation to performance, quality, safety and efficacy? (excluding routine premarket evaluation) **or**
- further restrictions or conditions, relating to the fitness for use of these devices for certain purposes or categories of patients following supply? (other than normal indications and contra-indications in published product information).

by overseas regulatory authorities? **Yes** ☐ **No** ☑

If **Yes**, please attach details.

- **Sponsors must be aware of their post market responsibilities for this product. Post market responsibilities are set out in the Standard Conditions document issued to sponsors when their goods are included in the ARTG.**

Individual Product details *(registration and listing applicants to complete)*

If there are additional individual products included in this application, photocopy this page and submit with this form.

29 **Product trade name and model number(s) as it appears on the label**

Co Cr Femoral Head

30 **ECRI IMD code ©**
(refer note opposite)

31 **Brief description of product**
(refer note opposite)

Femoral Head 28mm and 32mm

32 **Sterile Goods**

What product information has been sent with this application?

Unit labels	☑	(Compulsory for the initial application)
Outer package label	☑	(Compulsory for the initial application)
Package insert	☐	(Compulsory for goods sold over the counter)
Promotional material	☐	(Compulsory for goods sold over the counter)
Instructions for use	☐	(Compulsory for registrable devices, optional for listable devices)
User manual	☐	(Compulsory for registrable devices, optional for listable devices)
Brochure(s)	☐	(Optional but recommended)

33 **Non-Sterile Goods**

What product information has been sent with this application?

Outer package label or compliance plate	☐	(Compulsory for the initial application)
Package insert	☐	(Compulsory for registerable goods and for goods sold over the counter)
Promotional material	☐	(Compulsory for registerable goods and for goods sold over the counter)
Instructions for use	☐	(Compulsory for registerable devices, optional for listable devices)
User manual	☐	(Compulsory for registerable devices, optional for listable devices)
Brochure(s)	☐	(Compulsory for registerable devices, optional for listable devices)

34 **Is this product or any of its components supplied sterile?** *(refer note opposite)*

Yes ☑ No ☐

If **Yes,** indicate by what means

- Steam ☐
- Ethylene oxide ☐
- Filtration ☐
- Gamma irradiation ☑
- Glutaraldeyde ☐
- Dry heat ☐
- Electron beam ☐
- Other ☐

Please specify

35 **Was material of human or other animal origin used in the manufacture or formulation of this product?** *(refer note opposite)*

Yes ☐ No ☑ N/A ☐

If **Yes,** give species type(s)

Specify country of origin of human/animal material

36 **Proposed shelf life of product**
(refer note opposite)

- 1 year ☐
- 2 years ☐
- 3 years ☐
- 4 years ☐
- 5 years ☑
- Other ☐

Please specify

37 **Proposed storage temperature of product**
(refer note opposite)

store below 8 degrees Celsius (refrigerate) ☐

store at 2 to 8 degrees Celsius (refrigerate – do not freeze) ☐

store below 25 degrees Celsius ☐

store below 30 degrees Celsius ☐

Other ☐

Please specify NOT APPLICABLE

38 **Is this product a kit/tray/pack/system?** **Yes** ☐ **No** ☑ *Go to question* **40**

Kits, Trays, Packs or Systems *(registration and listing applicants to complete)*

39 **List of therapeutic goods contained in the Kit/Tray/Pack/ System**

	Description	AUST R or AUST L number	ECRI IMD code ©
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

Medicated or Formulated devices *(registration and listing applicants to complete)*

40 **Is this a medicated or formulated device?** *(refer list opposite)*

Yes ☐ **No** ☑

If contact lens solution, disinfectant/sterilant or hydrogel wound dressing go to question 42

41 **Ingredients of medicated or formulated devices other than contact lens solutions, disinfectants/sterilants and hydrogel wound dressings.** *(refer note opposite)*

Name	
Quantity	
Name	
Quantity	
Name	
Quantity	
Name	
Quantity	
Name	
Quantity	
Name	
Quantity	

Checklist

Where requested, have you provided the following:

- [ ] "Enterprise Details" form – if not previously submitted.
- [x] Cheque for the applicable fee in Australian dollars.
- [ ] Additional pages of manufacturers.
  If so, how many manufacturers are included in this application? [ ]
- [x] Evidence of quality systems/GMP certification for overseas manufacturers included in this application (if applicable).
- [ ] Copy of a current "Test Certificate" (where required).
- [ ] Supplementary page(s) for contact lens solutions, disinfectant/sterilant and hydrogel wound dressings formulation details (if applicable).
- [ ] Additional pages of individual product details.
  If so, how many individual products are included in this application? [ ]
- [x] Product literature or sample **(for sterile products please supply outer and unit pack labels).**
- [x] Details of regulatory record (if applicable).
- [ ] Details of material supporting variation (if applicable).
- [ ] Copy of "Instrument of Appointment" (if applicable). (see Enterprise Details form)
- [ ] Evaluation submission (if applicable) as per *"Australian Medical Device Requirements under the Therapeutic Goods Act 1989 – DR4"* for Registrable devices.

Send the complete form, together with the application fee and attachments to:

The Business Manager
Business Management Unit
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If this is an application for Registration of a Therapeutic Device send the original application to the address above and a copy with your submission for evaluation to:

Postal address

The Premarket Evaluation Manager
Medical Devices Section
Conformity Assessment Branch, TGA
PO Box 100
WODEN ACT 2606

Courier address

The Premarket Evaluation Manager
Medical Devices Section
Conformity Assessment Branch, TGA
136 Narrabundah Lane
SYMONSTON ACT 2609

It is the sponsor's responsiblility to ensure that this application is accompanied by all relevant documentation and if the application is for a registrable device, adequate data. This includes the appropriate application fee(s).

Applications which are incomplete or contain incorrect information are liable to be rejected under Subsection 23(2) of the *Therapeutic Goods Act 1989.*

OSTEOIMPLANT TECHNOLOGY, INC.
11201 PEPPER ROAD, HUNT VALLEY, MD 21031

Mr. John Green
Portland Orthopedics, Inc.
1239 N. High Street
Columbus, OH 43201

Re: OTI Product Lines, Regulatory Status

CERTIFICATION

All implants and related orthopedic instrumentation are cleared via 510(k) submiss by the US FDA for marketing in the USA and unrestricted export worldwide. The Quality System employed by OTI is in compliance with the U.S. CFR, Part 820, Quality System Regulations and other applicable regulatory documents. In additio Quality System received the ISO-9001/EN46001 Certification and all implants bea "CE0044" mark. The manufacturing facility is subject to U.S. FDA periodic inspe and mandatory annual ISO-9001/EN46001 Audits.

Sam Son,
Vice President of Technical Affairs,
Official Correspondent

ISO 9001 CERTIFICATIONS

CERTIFICATE

The TÜV CERT Certification Body of Rheinisch-Westfälischer TÜV e.V.

hereby certifies in accordance with TÜV CERT procedure that

OTI INC.
11201 Pepper Road, Hunt Valley
MD 21031 / USA

has established and applies a quality system for

Design, Manufacturing and Distribution of Orthopedic Implants and Accessories

An audit was performed, Report No. **3.0.1-1017/98**

Proof has been furnished that the requirements according to

ISO 9001 : 1994 / EN ISO 9001 : 1994 / EN 46001 : 1996

are fulfilled. The certificate is valid until **August 2001**

Certificate Registration No. **041058567**

Deutscher Akkreditierungs Rat DAR TGA-ZM-30-96-00

Deutscher Akkreditierungs Rat DAR TGA-ZM-13-96-11

Essen, 31.08.1998

RWTÜV

TÜV CERT Certification Body
of Rheinisch-Westfälischer TÜV e.V.

10/0144 rev4. 2x DAR RWTÜV 5.97

ZERTIFIKAT

CERTIFICATE

RWTÜV

Registrier-Nr./*Registered No.*:
04 207-2339/98

Anlage 1, Blatt 1 von 2
Annex 1, page 1 of 2

Zeichen des Auftraggebers *Reference of applicant*	Auftragsdatum *Date of application*	Aktenzeichen *File reference*	Prüfbericht Nr. *Test report No.*	Ausstellungsdatum *Date of issue*	Revision *revision:*
OTI, Inc.	31.05.98	3.1.1-876/98	2193/98	30.09.1998	0

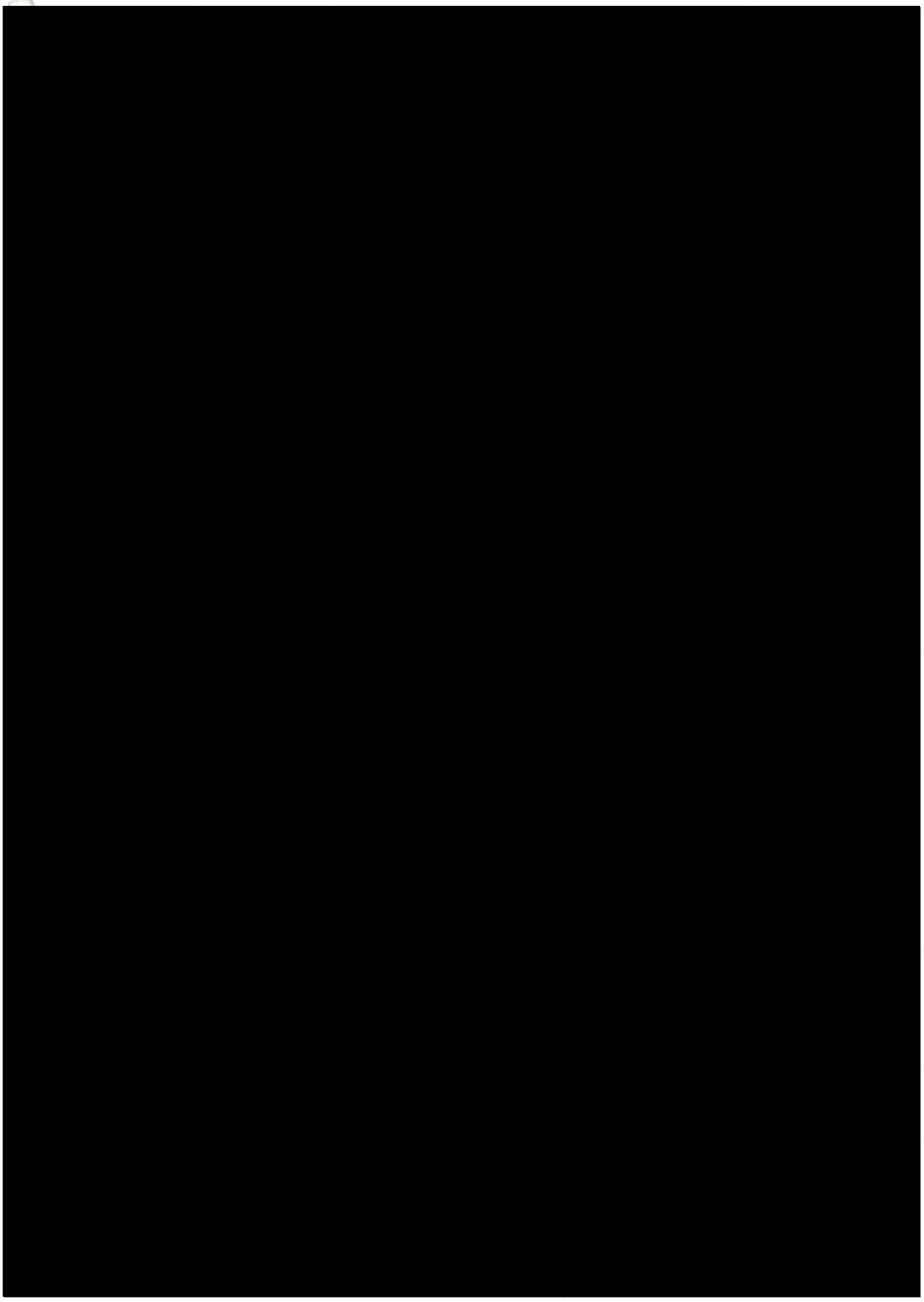
Orthopädische Implantate
Orthopedic Implants

Femoral Hip Systems	LSF	Series
	LSF-J	Series
	LSF-Triad	Series
	Omega	Series
	Biometric	Series
	Americana	Series
	Eurostem	Series
	Unifit Stem	Series
	Charnley Type	Series
	Moore Type	Series
	Mueller Type	Series
Acetabular Hip Systems	LSF	Series
	LSF-J	Series
	Alfa	Series
	Bipolar	Series
	Unipolar	Series
	Biometric	Series
Total Hip Accessories		
Bone Screws	TSC/TCS	Series
Bone Plugs	110	Series

Zertifizierungsstelle des RWTÜV e.V.
für Gerätesicherheit, Aufzüge
und Medizintechnik, notifiziert bei der
EG-Kommission unter Nr. 0044

COPY

Rheinisch-Westfälischer
Technischer Überwachungs-
Verein e.V., Sitz: Essen
Langemarckstraße 20
D-45141 Essen
Postfach 10 32 61
D-45032 Essen
Telephone +49/201 8 25-0
Telefax +49/201 8 25-33 56



ZERTIFIKAT

CERTIFICATE

RWTÜV

Registrier-Nr./*Registered No.:*
04 207-2339/98

Vollständiges Qualitätssicherungssystem gemäß 93/42/EWG Anhang II
Complete quality system according to 93/42/EEC annex II

Zeichen des Auftraggebers *Reference of applicant*	Auftragsdatum *Date of application*	Aktenzeichen *File reference*	Prüfbericht Nr. *Test report No.*	Ausstellungsdatum *Date of issue*	Gültigkeit bis *Expiry date*
OTI, Inc.	31.05.98	3.1.1-876/98	2193/98	30.09.98	30.09.01

Hiermit wird bestätigt, daß das Qualitätssicherungssystem des nachfolgend genannten Unternehmens den Maßgaben des Anhangs II, Abschnitt 3 der Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte für die Auslegung, die Fertigung und die Endkontrolle entspricht. Zusätzlich zur CE-Kennzeichnung muß die Kennnummer des RWTÜV e.V. angebracht werden. Dies kann in der nachfolgend abgebildeten Form erfolgen.
We hereby certify that the quality assurance system of the company mentioned below is in conformance with the requirements of annex II, paragraph 3 of the council Directive 93/42/EEC of 14 June 1993 relating to medical devices for design, production and final control. Additional to the CE-marking the notification number for RWTÜV e.V. has to be affixed. This can be done in the illustrated form.

CE 0044

Antragsteller:
Applicant:
OTI, Inc.
11201 Pepper Road
Hunt Valley, MD 21031 USA

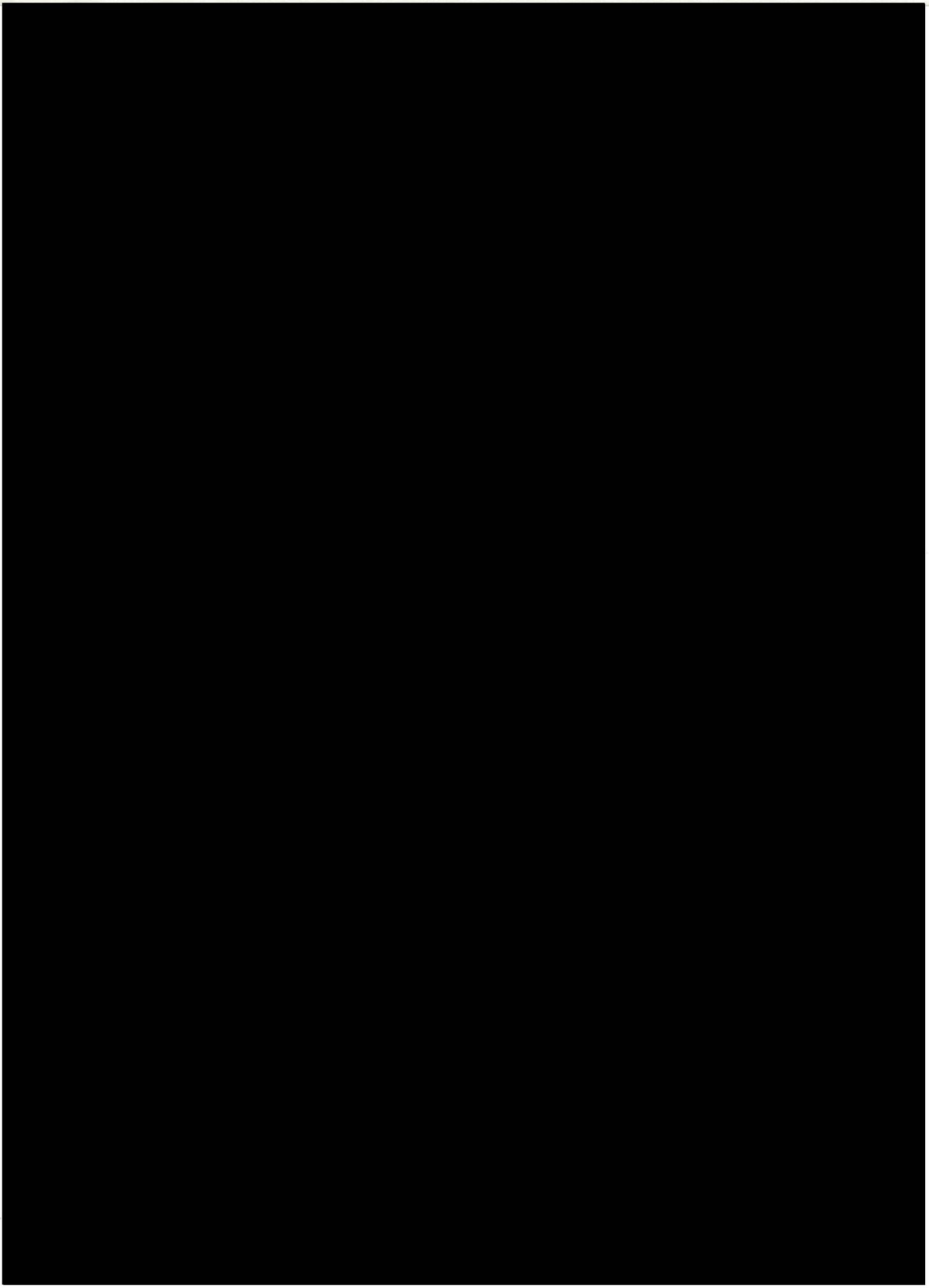
Fertigungsstätte:
Manufacturing plant:
OTI, Inc.
11201 Pepper Road
Hunt Valley, MD 21031 USA

Geltungsbereich:
Scope:
Entwicklung, Herstellung und Vertrieb von orthopädischen Implantaten und Zubehör
Design, Manufacturing and Distribution of Orthopedic Implants and Accessories

Liste der Produkte siehe Anlage 1 / *List of products see annex 1*

Zertifizierungsstelle des RWTÜV e.V.
für Gerätesicherheit, Aufzüge
und Medizintechnik, notifiziert bei der
EG-Kommission unter Nr. 0044

Rheinisch-Westfälischer
Technischer Überwachungs-
Verein e.V., Sitz: Essen
Langemarckstraße 20
D-45141 Essen
Postfach 10 32 61
D-45032 Essen
Telephone +49/201 8 25-0
Telefax +49/201 8 25-33 56



EUROPEAN DECLARATION OF CONFORMITY

CE

The undersigned hereby declares, on behalf of Osteoimplant Technology, Inc. of Hunt Valley, Maryland, that the above-referenced products, to which this declaration relates is in conformity with the provisions of Council Medical Device Directive (MDD) 93/42/EEC of June 14, 1993 and the following standards:

ISO-9001 Compliance
EN-46001 Compliance
FDA 21 CFR, Part 820, QSR
EN-552 Sterilization of Medical Devices by Irradiation
EN556 Sterilization of Medical Devices - requirements for devices labeled "Sterile"
EN980 Labeling for Medical Devices
EN 1441 FMEA
EN 30993 Biocompatability Standard

The Technical Construction File required by this Directive is maintained at the corporate headquarters of Osteoimplant Technology, Inc., 11201 Pepper Rd, Hunt Valley, Maryland, USA

The authorized representative located within the Community is:

Joaquin Forriol
LAFITT, S.A.
Valencia Parc Technologic
Edificio CEEI
Calle 3, s/n
46980 PATERNA - Valencia SPAIN
Phone: 96/ 199 42 44
Fax: 96/ 199 42 45

Date of Issue: MARCH 2, 1999

Place of issue: 11201 Pepper Road
Hunt Valley, Maryland 21031
USA

Sam Son
Vice President of Technical Affairs

SAMPLE LABELING

Cat. No.: PFH-028L **STERILE R**

Desc.: Margron™ Femoral Head
Long-Neck +3.5mm

Size: 28mm O.D. Qty: 1

XXXX XX XXXX XX LOT XXXX

Material: CoCr Alloy

Form No.: PL-IMPL-231-O Osteoimplant Technology, Inc.

Cat. No.: PFH-028M **STERILE R**

Desc.: Margron™ Femoral Head
Medium Neck +0mm

Size: 28mm O.D.

XXXX XX XXXX XX LOT

Material: CoCr Alloy

Form No.: PL-IMPL-231-O Osteoimplant Techn

Cat. No.: PFH-028S **STERILE R**

Desc.: Margron™ Femoral Head
Short Neck -3.5mm

Size: 28mm O.D. Qty: 1

XXXX XX XXXX XX LOT XXXX

Material: CoCr Alloy

Form No.: PL-IMPL-231-O Osteoimplant Technology, Inc.

Cat. No.: PFH-028XL **STERILE R**

Desc.: Margron™ Femoral Head
Ex-Long Neck +7.0mm

Size: 28mm O.D.

XXXX XX XXXX XX LOT

Material: CoCr Alloy

Form No.: PL-IMPL-231-O Osteoimplant Techn

Cat. No.: PFH-032L **STERILE R**

Desc.: Margron™ Femoral Head
Long-Neck +3.5mm

Size: 32mm O.D. Qty: 1

XXXX XX XXXX XX LOT XXXX

Material: CoCr Alloy

Form No.: PL-IMPL-231-O Osteoimplant Technology, Inc.

Cat. No.: PFH-032M **STERILE R**

Desc.: Margron™ Femoral Head
Medium Neck +0mm

Size: 32mm O.D.

XXXX XX XXXX XX LOT

Material: CoCr Alloy

Form No.: PL-IMPL-231-O Osteoimplant Techn

Cat. No.: PFH-032S **STERILE R**

Desc.: Margron™ Femoral Head
Short Neck -3.5mm

Size: 32mm O.D. Qty: 1

XXXX XX XXXX XX LOT XXXX

Material: CoCr Alloy

Form No.: PL-IMPL-231-O Osteoimplant Technology, Inc.

Cat. No.: PFH-032XL **STERILE R**

Desc.: Margron™ Femoral Head
Ex-Long Neck +7.0mm

Size: 32mm O.D.

XXXX XX XXXX XX LOT

Material: CoCr Alloy

Form No.: PL-IMPL-231-O Osteoimplant Techn

Manufactured by
Osteoimplant Technology, Inc.
for
Portland Orthopedics,Inc.
1239 N. High Street
Columbus, OH 43201
Telephone: 614-291-3473 Fax: 614-291-3468
Rev. O 09/06/00

RADIATION STERILIZATION CERTIFICATION

All OTI products are sterilized under the guidelines of the American National Standard ANSI/AAMI/ISO 11137. All OTI products receive a minimum absorbed dose of 25.0 kGy and maximum 50.0 kGy. A sample of typical certificate of Irradiation is attached.

CERTIFICATE OF IRRADIATION

COF

IRRADIATION LOT NUMBER: 08021034

IRRADIATED BETWEEN: 13:58 (TIME), 08/25/00 (DATE) AND 18:58 (TIME), 08/25/00 (DATE) (Dickerso

CUSTOMER
OTI, Inc.
11201 Pepper Rd
Hunt Valley, MD 21031

PURCHASE ORDER NO.:
7821

PRODUCT DESCRIPTION AND CUSTOMER RUN NUMBER
Orthopedic Implants (contains 107 pieces)
Product description attached, pages 2 through 4 of 4

Run #343

NUMBER OF CARTONS IN IRRADIATION LOT
3

ABSORBED DOSE SPECIFIED			ABSORBED DOSE MEASURED		
MINIMUM	25.0	kGy	MINIMUM	33.6	kGy
MAXIMUM	50.0	kGy	MAXIMUM	41.7	kGy

ABSORBED DOSE MEASURED BY FWT60-00 DOSIMETERS; UNCERTAINTY OF MEASUREMENT ± 3.8% AT A 95% CONFIDENCE LEVEL.

COMMENTS

Carol M. Campbell
Carol M. Campbell
QC Manager, Radiation Processing Servi

Date August 28, 2000

neutron products