

# CERTIFICATE

This certificate is endorsed by KEMA Quality B.V. in its capacity as Notified Body for European Directives 90/385/EEC, 93/42/EEC and 98/79/EC.

Number: 560064.001  
The Quality System of:

**IsoTis OrthoBiologics, Inc.**  
**2 Goodyear**  
**Irvine, CA 92618**  
**United States**

**Additional Facility:**

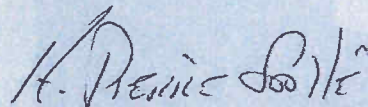
**IsoTis N.V.**  
**Prof. Bronkhorstlaan 10**  
**3723 MB Bilthoven**  
**The Netherlands**

Including its implementation, meets the requirements of the standard:

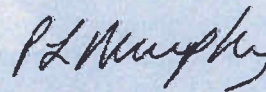
## ISO 13485:2003

Scope:  
Design, development, manufacture, distribution, marketing and sales of orthobiologic implants for orthopedic and maxillofacial applications.

Certificate Expiry Date:	September 26, 2011
Certificate Effective Date:	September 26, 2008
Certified for the first time:	September 26, 2002



H. Pierre Sallé  
President  
KEMA-Registered Quality



Patricia Murphy  
Certification Manager  
KEMA Quality B.V.

KEMA is a CMDCAS recognized registrar.  
Integral publication of this certificate is allowed

**KEMA-Registered Quality, Inc.**  
4377 County Line Road  
Chalfont, PA 18914 USA  
Ph: (215) 997-4519  
Fax: (215) 997-3809  
CRT 006 073004

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