Manufacturer Evidence

Status : Versioned

Certificate change history

Version 1: Accepted. Manufacturer's evidence processed as per 1/7/08. GMDN codes, intended purpose & classification will be assessed at point of application. MDaS has informed sponsor of accepted Manufacturers evidence.
Note: II.4 cert required for class III [redacted] 16/11/2009)

Date received :	10/11/2009
Certificate printed :	No

New Notification

Notification details

Evidence identifier:	DV-2009-MC-13143-3
Submission identifier:	DM-2009-05836-7
Version number:	1
Sponsor's own reference:	Lima Ortho Aust - Lima Lto Italy

Sponsor details

Agent name:	[redacted]
Sponsor name:	Lima Orthopaedics Australia Pty Ltd
Contact details:	[redacted]

Certification details

Manufacturer name:	Lima Lto SPA (Italy)[28937]
Manufacturer address as on certification:	Via Nazionale 52 Villanova di San Daniele UDINE 33030 Italy S [103905]

Type of product:
This certification is to support an application for a medical device that is not an in vitro diagnostic medical device (IVD)

Certificate issued under:	02
Conformity assessment procedure:	Schedule 3 Part 1 (Annex II)
Source of certification:	TUV SUD Product Service GmbH [0123]
Certificate number:	G1 07 04 19908 011
Certificate issue date: (dd/mm/yyyy)	13/04/2007
Certificate expiry date: (dd/mm/yyyy)	01/11/2011
Certificate re-issue date: (dd/mm/yyyy)	

Restrictions on scope:

Restriction on conformity assessment procedure:
Full Quality Assurance Certificate.
Note: For Class III a Design Examination Certificate must be submitted with the Device Application.

Attached documentation:

Attached documents	EC Certificate - ECCert G1070419908011Exp01112011.pdf

Supporting documents:			
#	Document Type	Description	Method

Related Active ARTG Entry Information:

History

CN=[redacted]OU=TGA/O=Health

16/11/2009

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC-CERTIFICATE

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 07 04 19908 011

Manufacturer:

LIMA LTO S.p.A.
Via Nazionale, 52
33038 Villanova di San Daniele (UDINE)
ITALY

Facility(ies):

LIMA LTO S.p.A.
Via Nazionale, 52, 33038 Villanova di San Daniele (UDINE), ITALY

LIMA LTO S.p.A.
Via Pinzano, 24, 33030 Flagogna (UD), ITALY

Product Category(ies):

ORTHOPEDIC IMPLANTS (foot, ankle, knee, hip, shoulder, elbow, wrist, hand, jaw, dental prostheses); TRAUMA SYSTEMS (fiches and wires for external fixators, internal fixators, nails, plates, screws, staples, ostheosynthesis); INSTRUMENTS in class IIa for orthopedics and trauma; kits for bone cement

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

Report No.: ITA 170075CN

Valid until: 2011-11-01

Date, 2007-04-13

Reiner Krumme

TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstrasse 65 · 80339 München · Germany