



FH*i*ndustrie

MANUFACTURER'S DECLARATION OF CONFORMITY AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

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FULL QUALITY ASSURANCE PROCEDURE

This is a declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the stated devices <or the devices stated in the attached Schedule.

Reference: Please refer to the list attached (1 page)

Manufacturer's Name: FOURNITURE HOSPITALIERE INDUSTRIE

Business Address: 6 Rue Nobel, Z.I. de Kernevez, 29000 Quimper, FRANCE

Medical Devices: LP ESP[®] Intervertebral disc

Classification: III

GMDN Code and Term: [P48165] Lumbar total disc replacement prosthesis

Scope of Application: A sterile implantable device designed to replace most or all of a dysfunctional intervertebral disc in the lumbar spine. It is typically made of metal or plastic-like (biopolymer) materials, or a combination of the two. It most commonly has a two-plate design, one plate attaching to the vertebra above and the other to the vertebra below. The device is intended to facilitate motion usually through the sliding action of its smooth surfaces..

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

Full Quality Management System Certificate:

LNE/G-MED Certificate no. 0401/B2P4/03 – Design examination - Annex II section 4 DIRECTIVE 93/42/EEC.

Design Examination Certificate:

ISO 13485: LNE/G-MED Certificate n°8808 -3 – Quality management system.

Standards Applied: European Harmonized Standard

Authorised Signatory:



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LP ESP® Intervertebral disc : Implant

Commercial reference	DESIGNATIONS
255682	PROTHESE DISCALE LP-ESP 7° EP 10MM
255683	PROTHESE DISCALE LP-ESP 7° EP 12MM
255687	PROTHESE DISCALE LP-ESP 9° EP 10MM
255688	PROTHESE DISCALE LP-ESP 9° EP 12MM
255690	PROTHESE DISCALE LP-ESP 11° EP 10MM
255691	PROTHESE DISCALE LP-ESP 11° EP 12MM