## ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE (90/385/EEC)

Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)

The Active Implantable Medical Devices Directive (with the official reference number 90/385/EEC) applies only to active implantable devices. For a device to be classified as an 'active implant', it must rely on a power source not provided by the body or gravity and be designed to be introduced into the body with the intention to remain there following the procedure.

The Active Implantable Medical Devices Directive has a a first objective the harmonization of the regulatory environment across the European Economic Area, and at the same time, it enables the free movement of goods within the European Union.

The Directive sets out the essential safety requirements in terms of function, sterility, material compatibility, marking, 'user' instructions, design documentation and CE marking but also include requirements for type approval, production quality management, clinical investigation and manufacturer registration.

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## WHICH PRODUCTS ARE COVERED BY THE ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE?

The Active Implantable Medical Devices Directive (90/385/EEC) covers medical devices that match the definition provided in the directive:

- 'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any accessories or software for its proper functioning, intended by the manufacturer to be used for human beings in the: diagnosis, prevention, monitoring, treatment or alleviation of disease or injury, investigation, replacement or modification of the anatomy or of a physiological process, control of conception, and which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means, but which may be assisted in its function by such means;
- 'active medical device' means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity;
- 'active implantable medical device' means any active medical device which is intended to be totally or partially introduced,

surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure;

## WHICH PRODUCTS ARE NOT COVERED BY THE ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE?

**Excluded from the Active Implantable Medical Devices Directive are:**

- in vitro diagnostic devices;
- active implantable devices covered by Directive 90/385/EEC;
- medicinal products covered by Directive 65/65/EEC;
- cosmetic products covered by Directive 76/768/EEC (18);
- human blood, human blood products, human plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells;
- transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin;
- transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or nonviable products derived from animal tissue.