



NSAI

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2012

The National Standards Authority of Ireland certifies that:

Harmac Medical Products, Inc.
2201 Bailey Avenue
Buffalo, NY 14211-1797
USA

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

The Design, Development, Manufacture and Contract Manufacturing of Disposable Medical Devices and Plastic Components and the Contract Manufacturing of Non-Active Implantable Medical Devices Including Devices Containing Tissue of Animal Origin.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4090)

Approved by:
Kevin D. Mullaney
Chief Executive Officer

Approved by:
Susan Murphy
Risk Management Officer

Registration Number: MD19.4090
Certification Granted: Sept 11, 2003
Effective Date: Dec 13, 2015
Expiry Date: Dec 12, 2018



National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800



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Annex to Certificate Number Cert/File No: MD19.4090

Scope of Registration :

The Design, Development, Manufacture and Contract Manufacturing of Disposable Medical Devices and Plastic Components and the Contract Manufacturing of Non-Active Implantable Medical Devices Including Devices Containing Tissue of Animal Origin.

Activity

Location

Headquarters, Administration,
Design and Development,
Distribution, Manufacture,
Warehouse

Harmac Medical Products, Inc.
2201 Bailey Avenue
Buffalo, NY 14211-1797
USA
File No.: MD19.4090

Headquarters, Administration,
Design and Development,
Distribution, Manufacture, Tissue
Manufacture, Warehouse

Harmac Medical Products
IDA Business Park
Castlerea
Co. Roscommon
Ireland
File No.: MD19.4090/A

Manufacture, Distribution,
Warehouse

Harmac Medical Products, Inc.
H3 de Tijuana, S. de RL de CV
Calle Maquiladoras No. 320-A
Col. Ciudad Industrial
Nueva Tijuana CP 22500
Mexico
File No.: MD19.4090/B

**Verified by:
Operations Manager**