



Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

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, Non-Active Implantable Medical Devices and Plastic Components.

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



Approved by:
Pamela Burdette Miller
Certification Manager

Registration Number: MD19.4090
Certification Granted: September 11, 2003
Effective Date: January 21, 2026
Expiry Date: December 12, 2027





Annex to Certificate Number: MD19.4090

Scope of Registration:

The Design, Development, Manufacture and Contract Manufacturing of Disposable Medical Devices, Non-Active Implantable Medical Devices and Plastic Components.

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 EU, Administration, Design and Development, Distribution, 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
Manufacture, Distribution, Warehouse	Harmac Medical Products, Inc. H3 de Tijuana, S. de RL de CV Presidentes 6002 Num. Int. 4, Colonia Rancho El Agulia Tijuana Mexico File No.: MD19.4090/C

Verified by:
Certification Manager