



NSAI

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:
Kevin Mullaney
Director of Certification

Registration Number: MD19.4090
Certification Granted: September 11, 2003
Effective Date: January 10, 2025
Expiry Date: December 12, 2027





NSAI

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
Castlereau
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

Distribution, Warehouse

Manufacture of Non-Sterile
Disposable Tubing Sets and Spikes.

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:
Director of Certification**