



Certificate of Registration of Quality Management System to 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. CM19.4090)



Approved by:

Pamela Burdette Miller
Certification Manager

Registration Number: CM19.4090

Certification Granted: September 11, 2003

Effective Date: January 21, 2026

Expiry Date: December 12, 2027



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National Standards Authority of Ireland, 20 Trafalgar Square, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412



Annex to Certificate Number: CM19.4090

Scope of Registration:

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

Activity

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

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

Manufacture, Distribution,
Warehouse

Manufacture, Distribution,
Warehouse

Location

Harmac Medical Products, Inc.
2201 Bailey Avenue
Buffalo, NY 14211-1797
USA
File No.: CM19.4090

Harmac Medical Products
IDA Business Park
Castlerea
Co. Roscommon
Ireland
File No.: CM19.4090/A

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.: CM19.4090/B

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.: CM19.4090/C

**Verified by:
Certification Manager**