



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



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

Location

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

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

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

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

Verified by:
Certification Manager