



# NSAI

## 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:

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**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:  
Kevin Mullaney  
Director of Certification

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Registration Number: CM19.4090  
Certification Granted: September 11, 2003  
Effective Date: January 10, 2025  
Expiry Date: December 12, 2027



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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



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## 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  
Castlereagh  
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

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.: CM19.4090/C

**Verified by:  
Director of Certification**