

# 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:

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

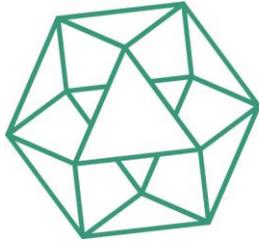
**Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4090)**

Approved by:  
Pamela Burdette Miller  
Certification Manager

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Registration Number: MD19.4090  
Certification Granted: September 11, 2003  
Effective Date: February 10, 2026  
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  
Castlereagh  
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  
C.P. 22444  
Tijuana, Baja California  
Mexico  
File No.: MD19.4090/B

Manufacture, Distribution,  
Warehouse

Harmac Medical Products, Inc.  
H3 de Tijuana, S. de RL de C.V.  
Presidentes 6002 Num. Int. 4  
Colonia Rancho El Aguila  
C.P. 22215  
Tijuana, Baja California  
Mexico  
File No.: MD19.4090/C

**Verified by:  
Certification Manager**