



# 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:

---

**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:  
Geraldine Larkin  
Chief Executive Officer

Approved by:  
Caroline Dore Geraghty  
Director of Medical Devices /  
Head of Notified Body

---

Registration Number: CM19.4090  
Certification Granted: September 11, 2003  
Effective Date: June 18, 2021  
Expiry Date: December 12, 2021



---

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



# NSAI

## **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

**Verified by:  
Operations Manager**