

# 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:

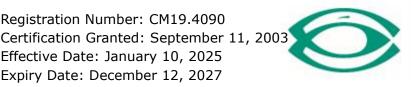
The Design, Development, Manufacture and **Contract Manufacturing of Disposable Medical Devices, Non-Active Implantable Medical Devices** and Plastic Components.

Additional sites covered under this multi-site certification are listed on the Annex (File No. CM19.4090)

Approved by: Kevin Mullaney Director of Certification

Registration Number: CM19.4090

Effective Date: January 10, 2025 Expiry Date: December 12, 2027









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

## Distribution, Warehouse

Manufacture of Non-Sterile Disposable Tubing Sets and Spikes.

## 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 Maguiladoras 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: **Director of Certification**