



# NSAI

## Certificate of Registration of Quality Management System to ISO 13485:2003

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 and Plastic Components and the Contract  
Manufacturing of Non-Active Implantable Medical  
Devices Including Devices Containing Tissue of  
Animal Origin.**

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

Approved by:  
Kevin D. Mullaney  
Chief Executive Officer

Approved by:  
John Bier  
Operations Manager

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Certificate Number: MD19.4090  
Certification Granted: Sep 11, 2003  
Effective Date: Dec 29, 2015  
Expiry Date: Dec 12, 2018



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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 MD19.4090

### Scope of Registration :

**The Design, Development, Manufacture and Contract Manufacturing of Disposable Medical Devices and Plastic Components and the Contract Manufacturing of Non-Active Implantable Medical Devices Including Devices Containing Tissue of Animal Origin.**

### 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, Administration,  
Design and Development,  
Distribution, Manufacture, Tissue  
Manufacture, Warehouse

Harmac Medical Products  
IDA Business Park  
Castlerea  
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  
Nueva Tijuana CP 22500  
Mexico  
File No.: MD19.4090/B

**Verified by:  
Operations Manager**