



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:

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:
Geraldine Larkin
Chief Executive Officer

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

Registration Number: MD19.4090
Certification Granted: September 11, 2003
Effective Date: June 18, 2021
Expiry Date: December 12, 2021





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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
Nueva Tijuana CP 22500
Mexico
File No.: MD19.4090/B

**Verified by:
Operations Manager**