



# NSAI

## Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

**HR Pharmaceuticals, Inc.**

**2600 Eastern Blvd**

**Suite 201**

**York, PA 17402**

**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, Manufacture and Distribution of Sterile and Non-Sterile Lubricating and Ultrasound Jelly**

**Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.8093)**

Approved by:  
Geraldine Larkin  
Chief Executive Officer

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

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Registration Number: MD19.8093  
Certification Granted: July 18, 2017  
Effective Date: February 20, 2019  
Expiry Date: December 31, 2021



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National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800



# NSAI

## Annex to Certificate Number: MD19.8093

### Scope of Registration:

**The Design, Manufacture and Distribution of Sterile and Non-Sterile Lubricating and Ultrasound Jelly**

#### Activity

#### Location

Headquarters, Design,  
Manufacturing, Distribution

HR Pharmaceuticals, Inc.  
2600 Eastern Blvd  
Suite 201  
York, PA 17402  
USA  
File No.: MD19.8093

Manufacturing

HR Pharmaceuticals, Inc.  
3630 Concord Road  
York, PA 17402  
USA  
File No.: MD19.8093/A

Warehouse

HR Pharmaceuticals, Inc.  
550 State Street  
York, PA 17402  
USA  
File No.: MD19.8093/B

**Verified by:  
Operations Manager**