



NSAI

Certificate of Registration of Quality Management System to 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:

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. CM19.8093)

Approved by:
Geraldine Larkin
Chief Executive Officer

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

Registration Number: CM19.8093
Certification Granted: July 18, 2017
Effective Date: February 20, 2019
Expiry Date: December 31, 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



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Annex to Certificate Number: CM19.8093

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.: CM19.8093

Manufacturing

HR Pharmaceuticals, Inc.
3630 Concord Road
York, PA 17402
USA
File No.: CM19.8093/A

Warehouse

HR Pharmaceuticals, Inc.
550 State Street
York, PA 17402
USA
File No.: CM19.8093/B

**Verified by:
Operations Manager**