



# NSAI

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

The National Standards Authority of Ireland certifies that:

**Monobind Inc.**  
**100 North Pointe Drive**  
**Lake Forest, CA 92630**  
**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 In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents, Controls, and Semi-Manual and Automated Washers and Analyzers.**

**Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4585)**

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: MD19.4585  
Certification Granted: May 18, 2010  
Effective Date: September 25, 2019  
Expiry Date: September 24, 2022





# NSAI

## **Annex to Certificate Number: MD19.4585**

### **Scope of Registration:**

**The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents, Controls, and Semi-Manual and Automated Washers and Analyzers.**

#### **Activity**

#### **Location**

Headquarters, Administration,  
Design, Manufacturing,  
Distribution

Monobind Inc.  
100 North Pointe Drive  
Lake Forest, CA 92630  
USA  
File No.: MD19.4585

Manufacturing, Distribution

Monobind Inc.  
103 North Pointe Drive  
Lake Forest, CA 92630  
USA  
File No.: MD19.4585/A

**Verified by:  
Operations Manager**