



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: C.R. Bard, Inc.

8195 Industrial Boulevard

Covington Georgia 30014 USA

Holds Certificate Number: FM 77109

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2003-09-04 Latest Revision Date: 2022-09-15

Expiry Date: 2024-12-22

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...making excellence a habit."

Effective Date: 2022-01-28

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Certificate No: FM 77109

Registered Scope:

The design, development, manufacture, sterilization, warehousing, distribution and marketing of Foley catheters and accessories (including procedural kits and trays) and bladder temperature measuring device(s), urinary drainage/collection devices and urine flow/volume measuring systems, urethral/intermittent catheters and accessories, ureteral catheter and accessories, urological guidewire and dilation products, suprapubic catheterization kits, percutaneous and suprapubic drains, ureteral stents, ureteroscopic and kidney stone removal devices and accessories, gastrointestinal drainage tubes and accessories (e.g., bile collection bags), fecal and urinary incontinence devices, bladder evacuator and accessories, ostomy products, wound suction/drainage products, compartmental pressure monitoring device(s), irrigation syringes, urine and mucous specimen devices, respiratory care products (e.g., endotracheal tubes, esophageal specialty tubes, latex airways, suction catheters), feeding tubes, skin and wound care products, securement devices for catheters, biopsy devices, electrosurgical devices for ablation and coagulation of tissue, specialty devices and bulking agents/delivery systems for incontinence; monitors and accessories for urodynamic evaluation of voiding dysfunctions, surgical tissue products, brachytherapy treatment devices and equipment, and pelvic prolapse repair products and accessories and temporary pacing electrode catheters. The incoming quality assurance and sterilization of products manufactured by and/or for all divisions of C.R. Bard, Inc.



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Certificate No:

FM 77109

Location

C.R. Bard, Inc. 8195 Industrial Boulevard Covington Georgia 30014 USA

C.R. Bard, Inc. 1211 Mary Magnan Boulevard Madison Georgia 30650 USA

Registered Activities

The design, development, manufacture, sterilization, warehousing, distribution and marketing of Foley catheters and accessories (including procedural kits and trays) and bladder temperature measuring devices, urinary drainage/collection devices and urine flow/volume measuring systems, urethral/intermittent catheters and accessories, ureteral catheter and accessories, urological guidewire and dilation products, suprapubic catheterization kits, percutaneous and suprapubic drains, ureteral stents, ureteroscopic and kidney stone removal devices and accessories, gastrointestinal drainage tubes and accessories (e.g. bile collection bags), fecal and urinary incontinence devices, bladder evacuator and accessories, ostomy products, wound suction/drainage products, compartmental pressure monitoring devices, irrigation syringes, urine and mucous specimen devices, respiratory care products (e.g. endotracheal tubes, esophageal specialty tubes, latex airways, suction catheters), feeding tubes, skin and wound care products, securement devices for catheters, electrosurgical devices for ablation and coagulation of tissue, specialty devices and delivery systems for incontinence; monitors and accessories for urodynamic evaluation of voiding dysfunctions, brachytherapy treatment devices and equipment, and pelvic prolapse repair products and accessories and temporary pacing electrode catheters. The incoming quality assurance, sterilization, warehousing and distribution of products manufactured by and/or for all divisions of C.R. Bard, Inc.

The sterilization of products manufactured by and/or for all divisions of C.R. Bard, Inc.

Original Registration Date: 2003-09-04 Effective Date: 2022-01-28 Latest Revision Date: 2022-09-15 Expiry Date: 2024-12-22

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