

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Ethicon, Inc.
1000 route 202
Raritan
New Jersey
08869
USA

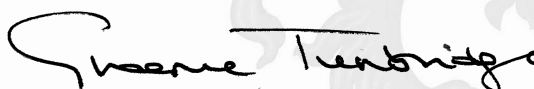
Holds Certificate Number:

FM 732364

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: 2020-07-10

Latest Revision Date: 2023-07-21

Effective Date: 2023-07-10

Expiry Date: 2026-07-09

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...making excellence a habit.™

Certificate No: FM 732364

Registered Scope:

Design and development, manufacture, packaging and distribution of sutures and ligatures (needled and non-needed, absorbable and non-absorbable, synthetic including stainless steel and non-synthetic, medicated and non-medicated), and suture cartridges (sterile), Surgical meshes (absorbable and non-absorbable, sterile), surgical mesh system (non-absorbable, sterile), Hemostasis devices (absorbable and non-absorbable, sterile), absorbable adhesion prevention devices composed of Oxidized Regenerated Cellulose ORC (sterile), tissue sealants and adhesives for internal and topical surgical applications (sterile), wound dressings (anti-microbial, sterile), surgical support tapes (absorbable & non-absorbable, sterile), umbilical cord tapes (sterile), Pelvic organ prolapse urogynaecological surgical mesh (sterile), cutaneous suturing needle (sterile, non-sterile), hysteroscopic systems including bipolar electrosurgical instruments and associated electrodes (sterile and non-sterile) and urinary stress incontinence devices (sterile and non-sterile), Surgical implant systems and devices, and tissue fixation devices (absorbable and non-absorbable, sterile) and accessories, Endoscopic and open instruments (sterile and non-sterile) and accessories, elastic tubing to secure veins, arteries, nerves and ureters (sterile), and fixation clips (sterile), Wound closure strips (sterile), Wound closure devices (sterile) and accessories, Urinary placement catheters (sterile). Other products including; closed wound drainage systems (sterile), delivery cannulas (sterile), temporary cardiac pacing wires (sterile), retention suture bridges (sterile), pledgets (sterile), surgical implants (sterile), surgical bone wax (sterile), electrosurgical Instruments and accessories (non-sterile), Design, development, production and distribution of Body Contouring Implants, Implantable Tissue Expanders, Accessories, and Sizers. Design, Development, Production, Servicing, and Distribution of Medical Devices for General Aspiration and Infiltration for Liposuction & Body Contouring. Sterilization services for other J&J company products. Distribution, packaging and labeling of devices on behalf of other J&J companies.

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Printed copies can be validated at www.bsigroup.com/ClientDirectory

Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

Contact Office: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA.

Certificate No: FM 732364

Location	Registered Activities
Ethicon, Inc. 655 Ethicon Circle Cornelia Georgia 30531 USA	The manufacture and distribution of raw materials for suture and specialty products from natural fibers, polymers, wire, stock, tissue sealants and adhesives for internal and typical surgical applications. Processes include polymer manufacture, extrusion, braiding, injection molding, needle forming, surface treatments, and the manufacture and packaging of surgical meshes (absorbable and non-absorbable).
Ethicon, LLC Highway 183 Km 8.3 San Lorenzo 00754 Puerto Rico	The manufacture, packaging and distribution of sutures and ligatures (needled and non-needled, absorbable and non-absorbable, synthetic including stainless steel and non-synthetic, non-medicated) and associated accessories (sterile), surgical support tapes (Non-absorbable) (sterile), temporary cardiac pacing wires (sterile), surgical mesh (non-absorbable) (sterile), pelvic organ prolapse urogynaecological surgical mesh (sterile), hemostasis devices (absorbable & non-absorbable) (sterile), absorbable adhesion prevention devices composed of Oxidized Regenerated Cellulose (ORC) (sterile), pledgets (sterile), polypropylene buttons (sterile), surgical bone wax (sterile), and tissue sealants and adhesives for internal and topical surgical applications (sterile) and endoscopic instruments (sterile) and Sterilization by dry heat of in-house products.
Ethicon, Inc. 3348 Pulliam Street San Angelo Texas 76905 USA	The manufacture, distribution and assembly of sutures and ligatures (needled and non-needled, absorbable, synthetic, medicated and non-medicated) and associated accessories (sterile), surgical meshes (absorbable) (sterile), wound closure devices (sterile) and tissue fixation devices (absorbable) and accessories (sterile). Sterilization of in-house products and other J&J company products.
Ethicon SARL Puits Godet 20 Neuchatel 2000 Switzerland	The Design and development, manufacture, packaging, storage and distribution of Absorbable adhesion prevention devices composed of Oxidized Regenerated Cellulose (ORC) (Sterile), Haemostasis Devices (Absorbable, Sterile), and Urinary Stress Incontinence Devices and accessories (Sterile & Non-Sterile).
Ethicon SARL Les Perveuils 10 Marin Epagnier CH-2074 Switzerland	The storage and distribution of absorbable adhesion prevention devices composed of Oxidized Regenerated Cellulose (ORC) (sterile), hemostasis devices (absorbable, sterile), and urinary stress incontinence devices and accessories (sterile & non-sterile).

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Location	Registered Activities
Ethicon, LLC 475 C Street Los Frailes Industrial Park Suite 401 Guaynabo 00969 Puerto Rico	The manufacture and distribution of sutures and ligatures (needled and non-needed, absorbable and non-absorbable, synthetic including stainless steel and non-synthetic, medicated and non-medicated) and associated accessories (sterile), suture cartridges (sterile), pledgets (sterile), umbilical cord tape (sterile), retention suture bridge (sterile), surgical support tapes (non-absorbable)(sterile), temporary cardiac pacing wires (sterile), tissue fixation devices (absorbable, sterile) and wound closure devices(stirle), elastic tubing to secure veins, arteries, nerves and ureters (sterile), fixation clips (sterile), and endoscopic instruments and accessories (non-sterile), surgical bone wax (sterile).
Ethicon, Inc 1420 Olympic Drive Athens Georgia 30601 USA	The manufacture of raw materials for suture from polymers. Processes include polymer manufacture and extrusion (absorbable and non-absorbable).

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Location	Registered Activities
Ethicon, Inc. 1000 route 202 Raritan New Jersey 08869 USA	Design and development, Regulatory Compliance of sutures and ligatures (needled and non-needled, absorbable and non-absorbable, synthetic including stainless steel and non-synthetic, medicated and non-medicated) and suture cartridges (sterile), Surgical meshes (absorbable and nonabsorbable, sterile), surgical mesh system (non-absorbable, sterile), Hemostasis devices (absorbable and non-absorbable, sterile), absorbable adhesion prevention devices composed of Oxidized Regenerated Cellulose ORC (sterile), tissue sealants and adhesives for internal and topical surgical applications (sterile), wound dressings (anti-microbial, sterile), surgical support tapes (absorbable & non-absorbable, sterile), umbilical cord tapes (sterile), Pelvic organ prolapse urogynaecological surgical mesh (sterile), cutaneous suturing needle (sterile, non-sterile), hysteroscopic systems including bipolar electrosurgical instruments and associated electrodes (sterile and non-sterile) and urinary stress incontinence devices (sterile and non-sterile), Surgical implant systems and devices, and tissue fixation devices (absorbable and non-absorbable, sterile) and accessories, Endoscopic and open instruments (sterile and non-sterile) and accessories, elastic tubing to secure veins, arteries, nerves and ureters (sterile), and fixation clips (sterile), Wound closure strips (sterile), wound closure devices (sterile) and accessories, Urinary placement catheters (sterile). Other products including; closed wound drainage systems (sterile), delivery cannulas (sterile), temporary cardiac pacing wires (sterile), retention suture bridges (sterile), pledgets (sterile), surgical implants (sterile), surgical bone wax (sterile), electrosurgical Instruments and accessories (non-sterile). Design, development of Body Contouring Implants, Implantable Tissue Expanders, Accessories, and Sizers and Medical Devices for General Aspiration and Infiltration for Liposuction & Body Contouring, Distribution, packaging and labelling of devices on behalf of other J&J companies.
Johnson & Johnson Medical (China) Ltd. No.75 Nangu Zhi Road Minhang Shanghai China	Design and Development, Production and Distribution of Silk Braided Non-absorbable Suture.

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Location	Registered Activities
Ethicon, Inc. Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chihuahua C.P. 32575 Mexico	Manufacture and assembly of sutures (needled and non-needled, absorbable and non-absorbable, synthetic including stainless steel and non-synthetic, medicated and non-medicated), and associated accessories (sterile), suture cartridges (sterile), Pledget (Sterile), umbilical cord tape (sterile), surgical support tapes (non-absorbable) (sterile), temporary cardiac pacing wires (sterile), wound closure devices (sterile), and tissue fixation devices (absorbable, sterile), elastic tubing to secure veins, arteries, nerves and ureters (sterile), fixation clips (sterile), and endoscopic instruments (non-sterile).
Johnson and Johnson Private Limited B 15/1, MIDC, Waluj Aurangabad Maharashtra 431 136 India	The design, development, manufacture & Distribution of Surgical Sutures, Polypropylene Meshes, Polypropylene Hernia system, Kits, tapes (Nylon, Polyester) and Sterilization by ethylene oxide of in-house products.
Johnson & Johnson International c/o European Logistics Centre Leonardo Da Vincilaan 15 BE-1831 Diegem Belgium	The design, development, manufacture and distribution of pledgets (sterile), surgical meshes (partially absorbable, absorbable, and non-absorbable) (sterile), surgical mesh systems (non-absorbable)(sterile), sutures and ligatures (needled and non-needled, absorbable and nonabsorbable, synthetic and non-synthetic, medicated and non-medicated), and associated accessories (sterile and non-sterile), and endoscopic instruments (non-sterile), wound closure devices (sterile), and accessories, surgical implants (sterile), surgical bone wax (sterile), and pelvic organ prolapse urogynaecological surgical mesh (sterile).
Johnson & Johnson MEDICAL GmbH Robert-Koch-Strasse 1 Norderstedt 22851 Germany	The design, development, manufacture and distribution of wound closure devices (sterile) and accessories, endoscopic and open instruments (non-sterile), electrosurgical instruments and accessories (non-sterile) and kits (sterile). Manufacture of suture and ligatures (needled and non-needled, absorbable and non-absorbable, synthetic, and non-synthetic, medicated and non-medicated) (sterile), surgical meshes (partially absorbable, absorbable and non-absorbable) (sterile), surgical mesh systems (non-absorbable) (sterile), pledgets (sterile), endoscopic and open instruments (non-sterile) and accessories, wound closures devices (sterile) and accessories, surgical implants (sterile), and pelvic organ prolapse urogynaecological surgical mesh (sterile), and synthetic absorbable sterile surgical implants to support the staple line, cutaneous suturing, needle (non-sterile). Sterilization by ethylene oxide and gamma irradiation of in-house products and other J&J company products.

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Location	Registered Activities
Johnson & Johnson MEDICAL GmbH Oststrasse 1 Norderstedt 22844 Germany	Repackaging and relabeling of finished products.
Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. Rod. Presidente Dutra - KM 154 São José dos Campos São Paulo 12240-908 Brasil	Manufacture of suture and ligatures (needled and non-needled, absorbable and non-absorbable, synthetic and non-synthetic, including those made of stainless steel and from animal tissue, medicated and non-medicated, sterile), surgical bone wax (sterile), surgical meshes (absorbable and non-absorbable) (sterile). Sterilization by ethylene oxide and gamma irradiation of in-house products and other J&J company products.
Mentor 3041 Skyway Circle North Irving Texas 75038 USA	Design, Development, Production, Servicing and Distribution of Body Contouring Implants, Sizers, and Medical Devices for General Aspiration, and Infiltration for Liposuction and Body Contouring.
Mentor 555 Airline Drive Coppell Texas 75019 USA	Distribution and repackaging of Body Contouring Implants, Sizers, and Medical Devices for General Aspiration, and Infiltration for Liposuction, & Body Contouring. Distribution, packaging and labeling of devices on behalf of other J&J companies.

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