

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

IPAX, Inc.
2700 South Raritan Street
Englewood
Colorado
80110
USA

Holds Certificate No:

FM 637536

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

Manufacturer and Contract Manufacturer for assembly, packaging and repackaging of sterile and non-sterile medical devices; Surgical Instruments, Laparoscopic Instruments, Ophthalmic Instruments, Palliative Medical Trays and Kits, Reconstruction Medical Trays and Kits, Intravenous Solution Delivery Sets and Extensions, and Medical Devices for Organ Transplant Management.

For and on behalf of BSI:



Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 2015-08-25

Latest Revision Date: 2018-08-30

Effective Date: 2018-09-11

Expiry Date: 2021-09-10

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