

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Imaxeon Pty Ltd
Unit 1
38-46 South Street
Rydalmere
New South Wales
2116
Australia

Holds Certificate Number:

MD 623422

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

Design and Development, Production, Distribution of Contrast Media Injector Systems, Sterile Injection Syringes and Radiographic Tubing.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2015-01-09

Latest Revision Date: 2019-09-30

Effective Date: 2019-10-04

Expiry Date: 2022-10-03

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