By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Nelipak Healthcare Packaging
5235 W Coplay Road
Whitehall
Pennsylvania
18052
USA

Holds Certificate Number: FM 680415

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

Manufacture & Custom Design Assistance of Thermoforming Packing Products for the Medical Device Industry

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-07-24
Effective Date: 2024-07-24
Latest Revision Date: 2026-10-16
Expiry Date: 2027-07-23

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Information and Contact:
BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780
BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.
America Headquarters: BSI Group America Inc. 1950 Opportunity Way, Suite 900, Reston, VA 20190.

Certificate No: FM 680415

Location	Registered Activities
NELIPAK HEALTHCARE PACKAGING 21 Amflex Drive Cranston Rhode Island 02921 USA	Design and manufacture of custom thermoformed plastic protective packaging and miscellaneous packaging components (such as sheaths, caps, etc.) for the medical industry.
Nelipak Healthcare Packaging 5235 W Coplay Road Whitehall Pennsylvania 18052 USA	Manufacture of Thermoformed Packaging Products for the Medical Device Industry.
Nelipak Healthcare Packaging 41 Comstock Pkwy Cranston Rhode Island 02921 USA	Receiving / storage of raw materials and storage of finished product.
Nelipak Healthcare Packaging 3720 W. Washington Street Phoenix Arizona 85009 USA	Manufacture of Thermoformed Packaging Products for the Medical Device Industry.
Nelipak Healthcare Packaging 180 Calle Cacique Jumacao Humacao 00791-5607 Puerto Rico	Manufacture of Thermoforming Packing Products for the Medical Device Industry.
Nelipak Healthcare Packaging Green Valley Grecia Alajuela Costa Rica	Manufacture of Thermoforming Packing Products for the Medical Device Industry.

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