

# 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 No:

**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:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2018-07-24

Latest Revision Date: 2018-12-19

Effective Date: 2018-07-24

Expiry Date: 2021-07-23

Page: 1 of 2



...making excellence a habit.™

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 & Custom Design Assistance of Thermoforming Packing 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 745 S Greensboro St Liberty North Carolina 27298 USA	Manufacture & Custom Design Assistance of Thermoforming Packing Products for the Medical Device Industry
Nelipak Healthcare Packaging 3720 Washington Street Phoenix Arizona 85009 USA	Manufacture and Custom Design of Thermoforming Packing Products for the Medical Device Industry.
Nelipak Healthcare Packaging 1200 Parkway, Global Park Heredia Costa Rica	Manufacture of Thermoforming Packing 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.

Original Registration Date: 2018-07-24

Effective Date: 2018-07-24

Latest Revision Date: 2018-12-19

Expiry Date: 2021-07-23

Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.