



Certificate No. 535-10-2025-1

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Four Pages)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from October 22, 2025 to October 21, 2027.



To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.fda.gov/fecv/CDRH.



Certificate No. 535-10-2025-1

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator

Bone Foam Inc.
20175 County Rd 50
Corcoran, MN
USA 55340

Name of Manufacturer

BONE FOAM INC.
20175 County Road 50
Corcoran, MN
USA 55340

Name of Distributor

BONE FOAM INC.
20175 County Road 50
Corcoran, MN
USA 55340

----END OF MANUFACTURER/DISTRIBUTOR LIST----





Certificate No. 535-10-2025-1

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 4

Name of Owner Operator

Bone Foam Inc.
20175 County Rd 50
Corcoran, MN
USA 55340

Name of Manufacturer

BONE FOAM INC.
20175 County Road 50
Corcoran, MN
USA 55340

Name of Product(s)

925.SAS-WS Arm Guard (f/k/a Single Arm Support with Straps) - Support, Patient Position
925.SAS-WS-BX10 Arm Guard | Box of 10 (f/k/a Single Arm Support - Box of 10) - Support, Patient Position
104.SLPS-AB Ax Bump (f/k/a Lateral Lumbar Positioning System Axillary Bolster) - Support, Patient Position
925.UEBL Block | Upper Extremity | Large (f/k/a Upper Extremity Block Large) - Support, Patient Position
925.UEBS Block | Upper Extremity | Small (f/k/a Upper Extremity Block Small) - Support, Patient Position
925.5CB Bump | Cylindrical | 5" (f/k/a 5" Cylindrical Bump) - Support, Patient Position
925.7CB Bump | Cylindrical | 7" (f/k/a 7" Cylindrical Bump) - Support, Patient Position
925.9CB Bump | Cylindrical | 9" (f/k/a 9" Cylindrical Bump) - Support, Patient Position
925.DLS-WS Duall (f/k/a Dual Leg Support with Strap) - Support, Patient Position
104.LHS Head Guard (f/k/a Lateral Head Support) - Support, Patient Position
104.LHS-BX10 Head Guard | Box of 10 (f/k/a Lateral Head Support - Box of 10) - Support, Patient Position
104.SLPS-HB Hip Bump (f/k/a Lateral Lumbar Positioning System Hip Bolster) - Support, Patient Position
925.HIPPY Hippy (f/k/a Direct Anterior Hip Positioning System) - Support, Patient Position
925.HIPPY-BP Hippy | Base Package (f/k/a Direct Anterior Hip Positioning System Base Package) - Support, Patient Position
925.HIPPY-DBC-BX20 Hippy | Disposable Barrier Cover | Box of 20 (f/k/a Disposable Barrier Cover - Box of 20) - Bedding, Disposable, Medical
925.HIPPY-HB Hippy | Hip Bolster (f/k/a Direct Anterior Hip Positioning System Hip Bolster) - Support, Patient Position
925.HIPPY-LB Hippy | Leg Board (f/k/a Direct Anterior Hip Positioning System Leg Board) - Support, Patient Position
925.HIPPY-LEP Hippy | Lower Extremity Package (f/k/a Direct Anterior Hip Positioning System Lower Extremity Package) - Support, Patient Position
925.HIPPY-PPBP-L Hippy | Padded Peg Board Post Large (f/k/a Direct Anterior Hip Positioning System Padded Peg Board Po...) - Support, Patient Position
925.HIPPY-PPBP-S Hippy | Padded Peg Board Post Small (f/k/a Direct Anterior Hip Positioning System Padded Peg Board Po...) - Support, Patient Position
925.HIPPY-TB Hippy | Torso Base (f/k/a Direct Anterior Hip Positioning System Torso Base) - Support, Patient Position
925.KBEX Knee Buddy (f/k/a Knee Buddy Extender) - Orthosis, Limb Brace
925.KBEX-BX4 Knee Buddy | Box of 4 (f/k/a Knee Buddy Extender - Box of 4) - Orthosis, Limb Brace
925.ERLE-R Leg Buddy (f/k/a Edema Reduction Leg Elevator Regular) - Orthosis, Limb Brace
925.ERLE-R-BX3 Leg Buddy | Box of 3 (f/k/a Edema Reduction Leg Elevator Regular - Box of 3) - Orthosis, Limb Brace
925.ERLE-HC Leg Buddy Heel Cut (f/k/a Edema Reduction Leg Elevator Heel Cut) - Orthosis, Limb Brace
925.ERLE-HC-BX3 Leg Buddy Heel Cut | Box of 3 (f/k/a Edema Reduction Leg Elevator Heel Cut - Box of 3) - Orthosis, Limb Brace
925.LC Leg Cradle (f/k/a Leg Cradle) - Support, Patient Position
925.LLB Leg Guard (f/k/a Lateral Leg Bolster) - Support, Patient Position
925.LLB-BX5 Leg Guard | Box of 5 (f/k/a Lateral Leg Bolster - Box of 5) - Support, Patient Position
925.LLT2-WS Leg Tunnel | Left (f/k/a Left Leg Tunnel with Straps) - Support, Patient Position
925.RLT2-WS Leg Tunnel | Right (f/k/a Right Leg Tunnel with Straps) - Support, Patient Position
925.ULT2-WS Leg Tunnel | Universal (f/k/a Universal Leg Tunnel with Straps) - Support, Patient Position
925.EH Limbo (f/k/a Extremity Holder) - Support, Patient Position
104.NPL Nextend | Lite - Support, Patient Position; Component, Traction, Non-Invasive





Certificate No. 535-10-2025-1

Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 4

104.NPLB Nextend | Lite | Bolster - Support, Patient Position
104.NPL-SUK Nextend | Lite | Single Use Kit - Component, Traction, Non-Invasive
104.NPL-SUK-BX5 Nextend | Lite | Single Use Kit | Box of 5 - Component, Traction, Non-Invasive
104.NPS-SB Nextend | Scapula Bolster (f/k/a Anterior Cervical Positioning System Scapula Bolster) - Support, Patient Position
104.NPS-SUK Nextend | Single Use Kit (f/k/a Anterior Cervical Positioning System - Single Use Kit) - Component, Traction, Non-Invasive
104.NPS-SUK-BX5 Nextend | Single Use Kit | Box of 5 (f/k/a Anterior Cervical Positioning System - Single Use K...) - Component, Traction, Non-Invasive
104.NPS Nextend | System (f/k/a Anterior Cervical Positioning System) - Support, Patient Position; Component, Traction, Non-Invasive
104.NPSB Nextend | System | Bolster - Support, Patient Position
104.NPS-TB Nextend | Torso Base (f/k/a Anterior Cervical Positioning System Torso Base) - Support, Patient Position
104.NPS-TA Nextend | Traction Anchor (f/k/a Anterior Cervical Positioning System Traction Anchor) - Support, Patient Position
925.PC Pelvic Cradle - Support, Patient Position
925.PC-DBC-BX20 Pelvic Cradle | Disposable Barrier Cover | Box of 20 (f/k/a Disposable Barrier Cover - Box of 20) - Bedding, Disposable, Medical
925.PF-SSP Prone One (f/k/a Prone Foam - Superior Support Pad) - Protector, Skin Pressure
925.PF-SSP-BX6 Prone One | Box of 6 (f/k/a Prone Foam - Superior Support Pad - Box of 6) - Protector, Skin Pressure
925.PROPC-L PROP - Coated | Large (f/k/a Pelvic Raising Operative Positioner Coated - Large) - Support, Patient Position
925.PROPC-R PROP - Coated | Regular (f/k/a Pelvic Raising Operative Positioner Coated - Regular) - Support, Patient Position
925.PROP-L PROP - Disposable | Large (f/k/a Pelvic Raising Operative Positioner Disposable) - Support, Patient Position
925.PROP-L-BX5 PROP - Disposable | Large | Box of 5 (f/k/a Pelvic Raising Operative Positioner Disposable - Box of 5) - Support, Patient Position
925.PROP-R PROP - Disposable | Regular (f/k/a Pelvic Raising Operative Positioner Disposable) - Support, Patient Position
925.PROP-R-BX5 PROP- Disposable | Regular | Box of 5 (f/k/a Pelvic Raising Operative Positioner Disposable - Box of 5) - Support, Patient Position
925.TR Ramp (f/k/a The Ramp) - Support, Patient Position
925.PTR Ramp | Pediatric (f/k/a Pediatric Ramp) - Support, Patient Position
925.TRPP2 Ramp | Prone (f/k/a The Ramp Prone Positioner 2) - Support, Patient Position
925.SER Ramp | Semi-Extended (f/k/a Semi-Extended Ramp) - Support, Patient Position
925.TRS Ramp | Shorty (f/k/a The Ramp Shorty) - Support, Patient Position
925.SCTR Ramp | Surgery Center (f/k/a Surgery Center Ramp) - Support, Patient Position
925.PSCTR Ramp | Surgery Center | Pediatric (f/k/a Surgery Center Pediatric Ramp) - Support, Patient Position
925.SHARK-WS Shark | Regular (f/k/a Lateral Decubitus Arm & Torso Stabilizer) - Support, Patient Position
925.SHARK-S-WS Shark | Small (f/k/a Lateral Decubitus Arm & Torso Stabilizer - Small) - Support, Patient Position
925.SG Shin Guard - Support, Patient Position
925.SG-BX10 Shin Guard | Box of 10 - Support, Patient Position
104.SLPS Sideline (f/k/a Lateral Lumbar Positioning System) - Support, Patient Position; Component, Traction, Non-Invasive
104.SLPS-LB Sideline | Lower Base (f/k/a Lateral Lumbar Positioning System Lower Base) - Support, Patient Position
104.SLPS-SUK Sideline | Single Use Kit (f/k/a Lateral Lumbar Positioning System - Single Use Kit) - Component, Traction, Non-Invasive
104.SLPS-SUK-BX5 Sideline | Single Use Kit | Box of 5 (f/k/a Lateral Lumbar Positioning System - Single Use Ki...) - Component, Traction, Non-Invasive
104.SLPS-TB Sideline | Torso Base (f/k/a Lateral Lumbar Positioning System Torso Base) - Support, Patient Position
925.MBL Tray Topper | Large (f/k/a Tray Topper Large) - Support, Patient Position
925.MBR Tray Topper | Regular (f/k/a Tray Topper Regular) - Support, Patient Position





Certificate No. 535-10-2025-1

Certificate to Foreign Government - Name of Product(s) Attachment Page 3 of 4

925.MBS Tray Topper | Small (f/k/a Tray Topper Small) - Support, Patient Position
10-910-12-C-I Troop | 2-Set (f/k/a Troop Elevation Pillow - Coated (2-set)) - Support, Patient Position
10-910-13-C-I Troop | 3-Set (f/k/a Troop Elevation Pillow - Coated (3-set)) - Support, Patient Position
10-911-09-C Troop | Arm Board Pad (f/k/a Arm Board Pad - Coated (with arm board strap)) - Support, Patient Position
10-910-07-C Troop | Arm Board Pad | Set of 2 (f/k/a Arm Board Pad - Coated - Set of 2) - Support, Patient Position
10-910-06-C Troop | Complete System (f/k/a Troop Elevation Pillow - Complete System) - Support, Patient Position; Bedding, Disposable, Medical
10-911-02 Troop | Disposable Barrier Cover (f/k/a Disposable Barrier Cover) - Bedding, Disposable, Medical
10-910-03 Troop | Disposable Barrier Cover | Box of 30 (f/k/a Disposable Barrier Cover - Box of 30) - Bedding, Disposable, Medical
10-911-06-C Troop | Elevation Pillow - Coated (f/k/a Troop Elevation Pillow - Coated) - Support, Patient Position
10-911-07-C Troop | Elevation Pillow Addition - Coated (f/k/a Troop Elevation Pillow Addition - Coated) - Support, Patient Position
10-911-00 Troop | Elevation System - Disposable (f/k/a Troop Elevation Pillow...) - Support, Patient Position; Bedding, Disposable, Medical
10-910-00 Troop | Elevation System - Disposable | Box of 3 (f/k/a Troop Elevation Pillow...) - Support, Patient Position; Bedding, Disposable, Medical
10-911-08-C Troop | Head Cradle - Coated (f/k/a Head Cradle - Coated) - Support, Patient Position
10-910-02-C Troop | Head Cradle - Coated | Box of 4 (f/k/a Head Cradle - Coated - Box of 4) - Support, Patient Position
10-911-08 Troop | Head Cradle - Disposable (f/k/a Head Cradle - Disposable) - Support, Patient Position
10-910-02 Troop | Head Cradle - Disposable | Box of 4 (f/k/a Head Cradle - Disposable - Box of 4) - Support, Patient Position
10-910-01-C Troop | Standard System (f/k/a Troop Elevation Pillow - Standard System) - Support, Patient Position; Bedding, Disposable, Medical
925.UPS-DBC-BX20 Universal Prone | Disposable Barrier Cover | Box of 20 (f/k/a Universal Prone Solution...) - Bedding, Disposable, Medical
925.UPS-L Universal Prone | Large - Support, Patient Position; Bedding, Disposable, Medical
925.UPS-L-DBC-BX20 Universal Prone | Large | Disposable Barrier Cover | Box of 20 - Bedding, Disposable, Medical
925.UPS-L-LB Universal Prone | Lower Body | Large - Support, Patient Position
925.UPS-R-LB Universal Prone | Lower Body | Regular (f/k/a Universal Prone Solution - Regular Lower Body) - Support, Patient Position
925.UPS-S-LB Universal Prone | Lower Body | Small (f/k/a Universal Prone Solution - Small Lower Body) - Support, Patient Position
925.UPS-R Universal Prone | Regular (f/k/a Universal Prone Solution - Regular (with Disp...)) - Support, Patient Position; Bedding, Disposable, Medical
925.UPS-S Universal Prone | Small (f/k/a Universal Prone Solution - Small (with Disposab...)) - Support, Patient Position; Bedding, Disposable, Medical
925.UPS-L-UB Universal Prone | Upper Body | Large - Support, Patient Position
925.UPS-R-UB Universal Prone | Upper Body | Regular (f/k/a Universal Prone Solution - Regular Upper Body) - Support, Patient Position
925.UPS-S-UB Universal Prone | Upper Body | Small (f/k/a Universal Prone Solution - Small Upper Body) - Support, Patient Position
925.AAKWL Wedge | Acute Knee | Large (f/k/a Acute Angle Knee Wedge Large) - Support, Patient Position
925.AAKWM Wedge | Acute Knee | Medium (f/k/a Acute Angle Knee Wedge Medium) - Support, Patient Position
925.AAKWS Wedge | Acute Knee | Small (f/k/a Acute Angle Knee Wedge Small) - Support, Patient Position
925.LW Wedge | Lateral (f/k/a Lateral Wedge) - Support, Patient Position
925.LWS Wedge | Lateral | Shorty (f/k/a Lateral Wedge Shorty) - Support, Patient Position
925.LUEWL Wedge | Left Upper Extremity | Large (f/k/a Left Upper Extremity Wedge Large) - Support, Patient Position
925.LUEWS Wedge | Left Upper Extremity | Small (f/k/a Left Upper Extremity Wedge Small) - Support, Patient Position
925.OAKWL Wedge | Obtuse Knee | Large (f/k/a Obtuse Angle Knee Wedge Large) - Support, Patient Position
925.OAKWS Wedge | Obtuse Knee | Small (f/k/a Obtuse Angle Knee Wedge Small) - Support, Patient Position
925.RUEWL Wedge | Right Upper Extremity | Large (f/k/a Right Upper Extremity Wedge Large) - Support,





Certificate No. 535-10-2025-1

Certificate to Foreign Government - Name of Product(s) Attachment Page 4 of 4

Patient Position

925.RUEWS Wedge | Right Upper Extremity | Small (f/k/a Right Upper Extremity Wedge Small) - Support,

Patient Position

925.UUELW Wedge | Universal Upper Extremity (f/k/a Universal Upper Extremity Lateral Wedge) - Support,

Patient Position

925.ZDK Zero Degree Knee (f/k/a Zero Degree Knee) - Orthosis, Limb Brace

925.ZDK-BX12 Zero Degree Knee | Box of 12 (f/k/a Zero Degree Knee Disposable - Box of 12) - Orthosis, Limb
Brace

Name of Distributor

BONE FOAM INC.

20175 County Road 50

Corcoran, MN

USA 55340

Name of Product(s)

925.FGC-BX10 Face Guard Cushion - Box of 10 - Protector, Skin Pressure

925.FGH Face Guard Helmet - Support, Patient Position

925.FGM Face Guard Mirror - Support, Patient Position

925.FGS Face Guard Set (Helmet + Mirror) - Support, Patient Position

925.AAKWSB-BX20 Acute Angle Knee Wedge Sterile Bags (Box of 20) - Drape, Surgical, Exempt

925.CBSB-BX25 Cylindrical Bumps Sterile Bags (Box of 25) (f/k/a Sterile Bags Cylindrical Bumps (Box of 25)) -
Drape, Surgical, Exempt

925.TRSB-BX20 The Ramp Sterile Bags (Box of 20) (f/k/a The Ramp Sterile Bags (Box of 20) Fits 925.TR,

925.PTR, 925.SCTR) - Drape, Surgical, Exempt

925.MBSB-BX20 Tray Topper Sterile Bags (Box of 20) - Drape, Surgical, Exempt

-----END OF PRODUCT LIST-----

