

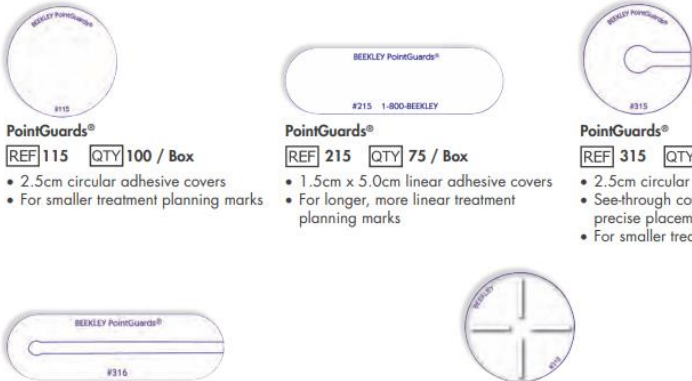

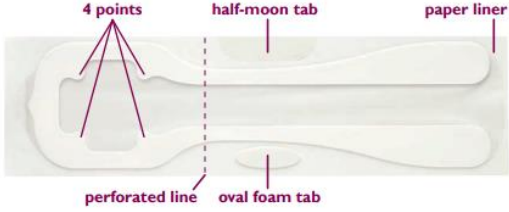
Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
Beekley Corporation	One Prestige Lane Bristol, Connecticut 06010 USA	US-MF-000007055

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Phone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	Code / Catalog Number	Basic UDI-DI
Bella Blankets®	310	00815137020230AT
Bella Blankets®	311	00815137020247BC
Cradles®	309	00815137020223AW
Pinnacle®	330	00815137020285BL
PointGuards®	115	00815137020056B3
PointGuards®	215	00815137021107B2
PointGuards®	315	00815137020254B9
PointGuards®	316	00815137020261B6
PointGuards®	318	00815137020278BP
TenderTouch™	418	00815137022043B8

Intended Purpose	Photo
<p>PointGuards Temporary Mark Covers are used for protecting treatment planning marks in radiation treatment.</p>	 <p>PointGuards® REF 115 QTY 100 / Box</p> <ul style="list-style-type: none"> • 2.5cm circular adhesive covers • For smaller treatment planning marks <p>PointGuards® REF 215 QTY 75 / Box</p> <ul style="list-style-type: none"> • 1.5cm x 5.0cm linear adhesive covers • For longer, more linear treatment planning marks <p>PointGuards® REF 315 QTY 100 / Box</p> <ul style="list-style-type: none"> • 2.5cm circular adhesive covers • See-through cover for quicker and more precise placement • For smaller treatment planning marks <p>PointGuards® REF 316 QTY 75 / Box</p> <ul style="list-style-type: none"> • 1.5cm x 5.0cm linear adhesive covers • See-through cover for quicker and more precise placement • For longer, more linear treatment planning marks <p>PointGuards® REF 318 QTY 85 / Box</p> <ul style="list-style-type: none"> • 2.5cm circular adhesive covers • Crosshair design • For hard to find marks
<p>Pinnacle Needle-Loc Needle Protectors are used for protecting and stabilizing the needle localization needle or cannula during breast biopsies.</p>	<p>Pinnacle® REF 330 QTY 12/box</p> 
<p>Cradles Needle Localization Wire Protectors are used for protecting and stabilizing the needle localization wire during breast biopsies.</p>	<p>Cradles REF 309 QTY 12/Box</p> <p>12" x 3" translucent cover with foam adhesive border</p> 

<p>Bella Blankets Protective Coverlets are used to protect the receptor plate and help with patient positioning to capture more breast tissue in mammography.</p>	<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p>REF 310 QTY 50 / Box Size: 22.9cm x 27.9cm Intended for use on 18cm x 24cm receptor plate</p> </div> <div style="text-align: center;">  <p>REF 311 QTY 50 / Box Size: 29.2cm x 33.0cm Intended for use on 24cm x 30cm receptor plate</p> </div> </div>
<p>TenderTouch cushioned tape is used for protecting the rough edges of cut thermoplastic masks due to patient claustrophobia, tightness, bite blocks, electron field, or bolus to provide patient comfort during head and neck radiation therapy treatments.</p>	<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  </div> <div style="text-align: center;">  <p>REF 418 QTY 200cm cut to measure roll / Box 2.5cm wide</p> </div> </div>

RISK CLASS FOR MEDICAL DEVICES		
Device Classification		Common Specifications / Standards
Class:	I	Optional
Rule:	1	

Beekley Corporation declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE: Kate B. Chase **SIGNATURE:** 
TITLE: Director of Quality & Regulatory **DATE:** 21/06/2021 **PLACE:** Bristol, CT 06010 USA