

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	1 Prestige Lane Bristol, CT 06010-7454 United States	US-MF-000007055

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Phone/email
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product Name	Code / Catalog Number
ColdSPOT®	500
ColdSPOT®	502
ColdSPOT®	505
Intended Purpose	Photo
<p>ColdSPOT Cold Therapy Packs are for targeted and effective cold treatment to reduce bleeding, bruising, pain, and inflammation.</p>	<p>ColdSPOT®</p> <p>REF 500 QTY 100 / Case • 2.75" x 3" gel pack • self-adhesive side tabs • for targeted and effective cold treatment following minimally invasive breast biopsy procedures</p> <p>ColdSPOT® with Floral Design</p> <p>REF 502 QTY 68 / Case • 2" x 3" advanced gel pack • self-adhesive side tabs • for targeted and effective cold treatment following minimally invasive breast biopsy procedures</p> <p>ColdSPOT® pillows</p> <p>REF 505 QTY 50 / Box • 2" x 3" advanced gel pack • soft, flexible fabric covering • self-adhesive side tabs • for targeted and effective cold treatment following minimally invasive breast biopsy procedures</p>

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

TITLE: Director of Quality & Regulatory

SIGNATURE:



PLACE: Bristol, CT 06010-7454 USA

DATE: 13/06/2023