

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
ColdSPOT®	500
ColdSPOT®	502
ColdSPOT®	505
Intended Purpose	Photo
ColdSPOT Cold Therapy Packs are for targeted and effective cold treatment to reduce bleeding, bruising, pain, and inflammation.	 <p>ColdSPOT® 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 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 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 USA

DATE: 25/10/2021