

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
Altus®	654	00815137020414B7
A-SPOT®	651	00815137020384BP
CT-SPOT®	118	00815137020070AV
CT-SPOT®	119	00815137020087BE
CT-SPOT®	120	00815137020094BB
CT-SPOT®	123	00815137020124AT
D-SPOT®	104	00815137020032AM
GuideLines®	117	00815137020063AY
GuideLines®	217	00815137021114AX
Localizers™	210	00815137020186BH
Localizers™	211	00815137021091BC
L-SPOT®	112	00815137020025AQ
Mark-Through GuideLines®	219	00815137021121AU
MR-SPOT®	121	00815137020100AD
MR-SPOT®	122	00815137020117AW
MR-SPOTS Packets™	184	00815137020148B9
MR-SPOTS Packets™	185	00815137020155B6
N-SPOT®	608	00815137020339BJ
N-SPOT®	610	00815137020353BC
N-SPOT®	632	00815137020360B9
N-SPOT®	653	00815137020407BA

N-SPOT®	690	00815137020438BM
N-SPOT®	732	00815137020469BY
N-SPOT®	790	00815137020537BQ
N-SPOT®	790P	00815137020544BM
ORTHO-SPOTS Packets™	186	00815137020162B3
O-SPOT®	609	00815137020346BF
O-SPOT®	652	00815137020391BL
O-SPOT®	691	00815137020445BJ
O-SPOT®	791	00815137020551BJ
PinPoint®	128	00815137020131AQ
PinPoint®	187	00815137020179BL
R-SPOT®	113	00815137020049B6
RT-SPOT®	127	00815137022142BB
S-SPOT®	607	00815137020322AZ
S-SPOT®	650	00815137020377BS
S-SPOT®	677	00815137020421B4
S-SPOT®	777	00815137020476BV
T-SPOT®	111	00815137021282BM
TomoSPOT®	781	00815137020483BS
TomoSPOT®	782	00815137020490BP
TomoSPOT®	783	00815137020506BD
TomoSPOT®	784	00815137020513BA
TomoSPOT®	785	00815137020520B7
V-SPOT®	603	00815137020315B4
V-SPOT®	703	00815137020452BF
X-SPOT®	101	00815137020001AA
X-SPOT®	601	00815137020292BH
Y-SPOT®	102	00815137020018AT
Y-SPOT®	602	00815137020308B7
Z-SPOT®	114	00815137021305B8

Intended Purpose	Photo
Skin Markers are designed to adhere to the skin to identify areas of interest on a radiographic image	

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: 21/06/2021