



## BioDerm, Inc. FDA Product Listings

**Proprietary Name:**

**CathGrip**

Classification Name:

ACCESSORIES, CATHETER

Product Code:

KGZ<sup>6</sup>

Device Class:

1

Regulation Number:

878.4200<sup>7</sup>

Medical Specialty:

General & Plastic Surgery

Registered Establishment Name:

BIODERM, INC.<sup>8</sup>

Registered Establishment Number:

1063299

Owner/Operator:

BIODERM,  
INC.<sup>9</sup>

Owner/Operator Number:

9032576

Establishment Operations:

Manufacturer

**Proprietary Name:**

**BioPlus Sterile**

Classification Name:

BANDAGE, LIQUID

Product Code:

KMF<sup>6</sup>

Device Class:

1

Regulation Number:

880.5090<sup>7</sup>

Medical Specialty:

General Hospital

Registered Establishment Name:

BIODERM, INC.<sup>8</sup>

Registered Establishment Number:

1063299

Owner/Operator:

BIODERM,  
INC.<sup>9</sup>

Owner/Operator Number:

9032576

Establishment Operations:

Specification Developer



## BioDerm, Inc. FDA Product Listings

**Proprietary Name:** **BioPlus Skin Wipe**

Classification Name: BANDAGE, LIQUID, SKIN PROTECTANT

Product Code: NEC<sup>6</sup>

Device Class: 1

Regulation Number: 880.5090<sup>7</sup>

Medical Specialty: General Hospital

Registered Establishment Name: BIODERM, INC.<sup>8</sup>

Registered Establishment Number: 1063299

Owner/Operator: BIODERM, INC.<sup>9</sup>

Owner/Operator Number: 9032576

Establishment Operations: Specification Developer

**Proprietary Name:** **Grip&Seal Catheter Securement Device; Grip&Seal Catheter Securement Device Sterile; Hold Me Catheter Securement Device; UniGrip Catheter Securement Device**

Classification Name: DEVICE, INTRAVASCULAR CATHETER SECUREMENT

Product Code: KMK<sup>6</sup>

Device Class: 1

Regulation Number: 880.5210<sup>7</sup>

Medical Specialty: General Hospital

Registered Establishment Name: BIODERM, INC.<sup>8</sup>

Registered Establishment Number: 1063299

Owner/Operator: BIODERM, INC.<sup>9</sup>

Owner/Operator Number: 9032576

Establishment Operations: Manufacturer



## BioDerm, Inc. FDA Product Listings

**Proprietary Name:** **BioDerm 2,000 mL Bag with Urimeter; BioDerm Urine Collection Bag 1,000 mL Sterile Fluid Pathway ; BioDerm Urine Collection Bag 2,000 mL Sterile Fluid Pathway**

Classification Name: BAG, URINE COLLECTION, LEG, FOR EXTERNAL USE, STERILE

Product Code: FAQ<sup>6</sup>

Device Class: 1

Regulation Number: 876.5250<sup>7</sup>

Medical Specialty: Gastroenterology

Registered Establishment Name: BIODERM, INC.<sup>8</sup>

Registered Establishment Number: 1063299

Owner/Operator: BIODERM, INC.<sup>9</sup>

Owner/Operator Number: 9032576

Establishment Operations: Specification Developer

**Proprietary Name:** **FreeDerm Adhesive Remover**

Classification Name: SOLVENT, ADHESIVE TAPE

Product Code: KOX<sup>6</sup>

Device Class: 1

Regulation Number: 878.4730<sup>7</sup>

Medical Specialty: General & Plastic Surgery

Registered Establishment Name: BIODERM, INC.<sup>8</sup>

Registered Establishment Number: 1063299

Owner/Operator: BIODERM, INC.<sup>9</sup>

Owner/Operator Number: 9032576

Establishment Operations: Specification Developer



**BioDerm, Inc. FDA Product Listings**

**Proprietary Name:** **BioDerm ECD and XLS; LIBERTY LP AND LS WITH INTEGRAL URINE COLLECTION CHAMBER; Liberty Safe and Dry LP and LS; ReliaFit Male Urinary Device; ReliaFit Male Urinary Device with CathGrip; Safe and Dry LP and LS**

Classification Name: DEVICE, PASTE-ON FOR INCONTINENCE, NON-STERILE

Product Code: NOA<sup>6</sup>

Device Class: 1

Regulation Number: 876.5250<sup>7</sup>

Medical Specialty: Gastroenterology

Registered Establishment Name: BIODERM, INC.<sup>8</sup>

Registered Establishment Number: 1063299

Owner/Operator: BIODERM, INC.<sup>9</sup>

Owner/Operator Number: 9032576

Establishment Operations: Contract Manufacturer; Manufacturer

**Proprietary Name:** **Extension Tube**

Classification Name: CONNECTOR, CATHETER

Product Code: GCD<sup>6</sup>

Device Class: 1

Regulation Number: 878.4200<sup>7</sup>

Medical Specialty: General & Plastic Surgery

Registered Establishment Name: BIODERM, INC.<sup>8</sup>

Registered Establishment Number: 1063299

Owner/Operator: BIODERM, INC.<sup>9</sup>

Owner/Operator Number: 9032576

Establishment Operations: Specification Developer



## BioDerm, Inc. FDA Product Listings

<b><u>Proprietary Name:</u></b>	<b><u>BioDerm Penis Clamp</u></b>
Classification Name:	CLAMP, PENILE
Product Code:	<u>FHA</u> <sup>6</sup>
Device Class:	1
Regulation Number:	<u>876.5160</u> <sup>7</sup>
Medical Specialty:	Gastroenterology
Registered Establishment Name:	<u>BIODERM, INC.</u> <sup>8</sup>
Registered Establishment Number:	1063299
Owner/Operator:	<u>BIODERM, INC.</u> <sup>9</sup>
Owner/Operator Number:	9032576
Establishment Operations:	Specification Developer