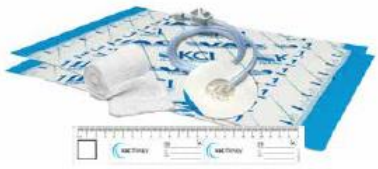
SCHEDA TECNICA

Marca	Immagine	Nome Commerciale
KCI AN ACELITY COMPANY		**KIT MEDICAZIONE CON GARZA MEDICATA PER NPWT**

DESCRIZIONE DEL PRODOTTO

Il kit con garza medicata per NPWT è concepito per l'utilizzo con le seguenti unità terapeutiche 3M: ActiV.A.C.™ e sistemi terapeutici V.A.C.®Ulta. Il sistema è concepito per creare un ambiente che favorisce la guarigione delle ferite per intenzione secondaria o terziaria (principale ritardata) preparando il letto della ferita per la chiusura, riducendo l'edema, favorendo la formazione di tessuto di granulazione e la perfusione, nonché rimuovendo l'essudato e il materiale infetto. È indicato per ferite croniche, acute, da trauma, subacute e deiscenti, ustioni a spessore parziale, ulcere (come quelle da diabete, da decubito o insufficienza venosa), lembi e innesti. La medicazione in garza per NPWT 3M non deve essere utilizzata per la terapia di instillazione, la terapia intermittente o sulle incisioni chiuse.

CARATTERISTICHE TECNICHE SALIENTI

Caratteristiche Principali	Il kit consta di: • Rotolo in garza Kendall Kerlix™ AMD™ trattato con PHMB 0.2% • Pellicola V.A.C.® (2 unità) • Righello V.A.C.® • Pad SensaT.R.A.C.™

CODICE, DESCRIZIONE, DIMENSIONI, CND, NR. REPERTORIO

Codice	Descrizione	Dimensioni Garza	Unità Minima di Vendita	Repertorio Registrato come kit assemblato	CND	Validità
418313	Kit Medicazione Garza medicata SensaT.R.A.C.™	3.7cmx11.4m	Confezione da 5 pezzi in blister singolo	132315	M040499	3 anni

CODICE, DESCRIZIONE, DIMENSIONI, CND, NR. REPERTORIO dei componenti del KIT

Codice	Descrizione	Repertorio	CND
3332	KERLIX AMD	1735636	M040499
419888	Kit SensaT.R.A.C.™	2111527	M040499

CE	LATEX	MR	PHT DEHP DEHP-free	STERILE R	
Conforme alla direttiva CEE/42/93) Nr. Certificato: CE 661656 ID Ente Certificatore: 2797	Latex Free	Compatibile con RMN	Non contiene DEHP	Sterilizzato con raggi gamma	Monouso

FABBRICANTE Kit SensaT.R.A.C.TM

KCI USA, Inc.
12930 IH 10 West
San Antonio
Texas
78294
USA

RAPPRESENTANTE EUROPEO

KCI Manufacturing Unlimited Company
IDA Business & Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 661656**

Issued To: **KCI USA, Inc.**
12930 IH 10 West
San Antonio
Texas
78249
USA

In respect of:

Design, development, and manufacture of powered and non-powered negative pressure wound therapy pumps and associated sterile foam dressing kits and tube sets, silver foam dressing kits, abdominal dressing kits, and electrically powered dermatome and associated accessories.
Those aspects of Annex II concerned with securing and maintaining the sterility of accessories for negative pressure wound therapy systems.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-03-03** Date: **2021-04-26** Expiry Date: **2024-05-26**

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Supplementary Information to CE 661656

Issued To:

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Number	Device Name	Intended purpose per IFU
Class III		
---	V.A.C.® GRANUFOAM SILVER™ DRESSINGS	See CE 673268
Class IIb		
GMDN 61145	V.A.C. VERAFLO™ Dressings	Negative pressure wound therapy dressings with instillation, for use on chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.
GMDN 58202	V.A.C. VIA™ Negative Pressure Therapy System	Negative pressure wound therapy pump, dressings, and canisters for use on chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.
GMDN 47406	V.A.C.® GRANUFOAM™ Dressings	Negative pressure wound therapy dressings for use on chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.

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Number	Device Name	Intended purpose per IFU
GMDN 47406	V.A.C. DERMATAC™ DRAPE with V.A.C.® GRANUFOAM™ DRESSINGS	Negative pressure wound therapy dressings for use on chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.
GMDN 47406	V.A.C. WHITEFOAM™ Dressings	Negative pressure wound therapy dressing for use on chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.
GMDN 47406	V.A.C.® SIMPLACE™ Dressings	Negative pressure wound therapy dressing for use on chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.
GMDN 47406	V.A.C.® GRANUFOAM™ Bridge Dressings	Negative pressure wound therapy dressing for use on chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.

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Number	Device Name	Intended purpose per IFU
GMDN 60884	Nanova Therapy System	Non-powered negative pressure wound therapy unit and dressings for use on chronic, acute, traumatic, subacute and dehisced wounds, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.
GMDN 47406	SNAP™ Dressings	Negative pressure wound therapy dressing for use on chronic, acute, traumatic, subacute and dehisced wounds, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.
Class IIa		
NBOG Codes MD 1100, MD 0100 and MDS 7006	V.A.C.ULTA™ Negative Pressure Wound Therapy System or V.A.C.ULTA 4 THERAPY Negative Pressure Wound Therapy System (with V.A.C.VeraLink Cassette and V.A.C.VeraT.R.A.C Duo)	---
NBOG Codes MD 1100	V.A.C.RX4™ Negative Pressure Wound Therapy System	---

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Number	Device Name	Intended purpose per IFU
NBOG Codes MD 1100	INFOV.A.C.™ Negative Pressure Wound Therapy System	---
NBOG Codes MD 1100	ActiV.A.C. Negative Pressure Therapy System	---
NBOG Code MD 0301 and MDS 7006	ABThera Open Abdomen dressings	---
NBOG Codes MD 1100	VAC Simplicity Negative Pressure Therapy Unit	---
NBOG Codes MD 1100, MD 0100 and MDS 7006	Cellutome Epidermal Harvesting System (Harvesters, Control Unit, Vacuum Head)	---
NBOG Codes MD 1100	SNAP™ Therapy Cartridge	---
NBOG Codes MD 1100, MD 0301 and MDS 7006	Prevena Incision Management System	---

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Number	Device Name	Intended purpose per IFU
NBOG Codes MD0301 and MDS 7006	V.A.C.® DERMATAC™ Drape	---
NBOG Code MD 0301 and MDS 7006	V.A.C.® Drape and SENSAT.R.A.C Pad accessory Kit	---
NBOG Code MD 0301 and MDS 7006	V.A.C.® Drape	---
Class Is		
NBOG Code MD 0100 and MDS 7006	V.A.C. Freedom Canisters	---
NBOG Code MD 0100 and MDS 7006	V.A.C.® Tubing Cap	---
NBOG Code MD 0100 and MDS 7006	SENSAT.R.A.C.™ Pad	---

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Number	Device Name	Intended purpose per IFU
NBOG Code MD 0100 and MDS 7006	V.A.C.® Y-connector	---
NBOG Code MD 0301 and MDS 7006	V.A.C.® Gel	---
NBOG Code MD 0100 and MDS 7006	Canisters for INFOV.A.C.™ and V.A.C. ULTA™ Therapy Systems	---
NBOG Code MD 0301 and MDS 7006	SNAP™ SecurRing Hydrocolloid	---
NBOG Code MD 0100 and MDS 7006	Canister for ACTIV.A.C. Therapy System	---

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Document Version: 1

Declaration of Mutual Compatibility

We,

KCI USA, Inc.
12930 IH 10 West
San Antonio, TX 78249 USA,

hereby declare that the product

Gauze Dressing with V.A.C. Therapy Accessory Kit featuring SensaT.R.A.C™ Technology

is classified according to Article 12 p.2 of the European Medical Device Directive 93/42/EEC as a procedure pack and that

- all medical devices included in the above procedure pack (1 x REF 3332, Kerlix™ AMD and 1 x REF 419888, V.A.C. Accessory Kit) are CE marked and the mutual compatibility of the devices have been verified,
- the manufacturer has packed the procedure pack and supplied relevant information to the users incorporating relevant instructions from the manufacturer(s),
- the whole activity is subjected to appropriate methods of internal control and inspection

Signature: Anona Goebel 21 May 2021

Anona Goebel
Manager, Regulatory Affairs
KCI USA, Inc.
12930 IH 10 West
San Antonio, TX 78249

Date