tyco Healthcare

Lotto N° 19

Tyco Healthcare Italia S.p.A.
Via Rivoltana 2/d - 20090 Segrate (MI) P.I. 08641790152
Rev.05 Agosto.2007

SCHEDA TECNICA
Curasorb

Nome Commerciale	**Curasorb**
Dispositivo Medico	**SI**
Codice	**Elenco codici a pag. 2**

Prodotto da Kendall, a division of Tyco Healthcare Group LP, Mansfield USA

Distribuito da Tyco Healthcare Italia SpA, Segrate (Mi)

Certificazione C.E. 0123 Organismo certificante TUV Product Services GMBH

Classe di appartenenza in conformità alla Direttiva Europea 93/42/EEC Classe IIb

Presenza Lattice	**NO**
Dispositivo Medico sterile	**Si**

Metodo di Sterilizzazione raggi gamma validità 4 anni dalla data di sterilizzazione

Descrizione completa
Medicazione in alginato di calcio e sodio, che a contatto con l'essudato della ferita gelifica creando un ambiente umido al sito della ferita.

Destinazione d'uso:
Le medicazioni Curasorb sono indicate nella gestione locale delle ferite esterne come per esempio ulcere da stasi, da pressione, ulcere arteriose, ulcere diabetiche, o lesioni simili che si manifestano con soluzione di continuo a carico del derma solo con intento secondario.

Materiale e Biocompatibilità:
Medicazione all'alginato di calcio e sodio a base di acido guluronico 68% ed acido mannuronico 32% in materiale naturale, con percentuale di impurezze inferiore al 2% e pH 6,5, ipoallegenico e biocompatibile.
Ad alta **capacità di assorbimento**: **Curasorb** assorbe, l'essudato proveniente dalla lesione, in quantità pari **a 21,3(g) per 100cm^2 deviazione standard 1,56**. Il **Curasorb Plus assorbe** l'essudato proveniente dalla lesione in quantità pari a **25,3 (g) per 100cm^2 deviazione standard 1,61.** Il tempo di permanenza sulla lesione varia al variare della quantità di essudato prodotto dalla lesione stessa; si consiglia di lasciarlo in sede per 2-4 giorni senza sostituzioni.
Il metodo utilizzato per misurare la capacità di assorbimento dei fluidi delle medicazioni è il SMTL, comunemente definito metodo del disco di Petri. In questo test, 400ml di soluzione di cloridrato di sodio e calcio contenete 142 millimoli (10^{-3}) di sodio, e 2,5 (10^{-3}) millimoli di ioni di calcio per litro, viene portata a 37°c in un bagno di acqua. Per esempio una medicazione che misura 5x5 cm, dal peso predeterminato viene posizionata in un disco di Petri e una soluzione test di volume uguale a 40 volte il peso del campione test, viene aggiunta al campione usando una pipetta. Il disco di Petri e il suo contenuto si lasciano scaldare a 37 +/- 0,5° C, per 30 +/- 1 minuti.

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Poi utilizzando una pinza, il campione viene rimosso dal disco di Petri, sospeso per 30 secondi e ribagnato. Il test viene ripetuto su 10 campioni. Dai risultati così ottenuti si calcola il peso della soluzione assorbita da 100 cm^2.
Considerando quindi una essudazione media ed uniformemente distribuita per un arco temporale di 4 giorni **la capacità di gestione dei fluidi** di **Curasorb** è la seguente:

Tempo	24 ore	48 ore	72 ore	96 ore
g/cm^2	5,325	10,65	15,975	21,3

Considerando quindi una essudazione media ed uniformemente distribuita per un arco temporale di 4 giorni **la capacità di gestione dei fluidi** di **Curasorb PLus** è la seguente:

Tempo	24 ore	48 ore	72 ore	96 ore
g/cm^2	6,324	12,64	18,97	25,29

Controindicazioni e Precauzioni:
leggere attentamente le istruzioni riportate sulla confezione

Modalità di conservazione:
Conservare in luogo asciutto e al riparo da fonti di calore
Trasporto e conservazione: da 0° a 50 °C.

Modalità di smaltimento:
Smaltire come rifiuto ospedaliero

Confezionamento:
Monouso
Confezionato singolarmente

Curasorb Plus

Codice	**Dimensioni**	**Conf/Scat**
9236	10 x 10 cm plus	50 Pezzi (5x10)

Curasorb

Codice	**Dimensioni**	**Conf/Scat**
9231	Nastro da 30 cm	50 Pezzi (5x10)
9232	5 x5 cm	50 Pezzi (5x10)
9233	10 x 10 cm	50 Pezzi (5x10)
9238	20 x 10 cm	50 Pezzi (5x10)
9239	15 x 25 cm	50 Pezzi (5x10)

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9240	10 x 14 cm	50 Pezzi (5x10)
9242	30 x 61 cm	5 Pezzi
9243	Nastro da 61 cm	50 Pezzi (5x10)
9244	Nastro da 91 cm	50 Pezzi (5x10)

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CURASORB
Tyco Healthcare

Presentazione:
nastro: varie misure
compressa sterile: varie misure

Azione:
medicazione primaria sterile a base di alginato di calcio e sodio. Non aderente, non tessuta, con fibre poste verticalmente rispetto al piano della medicazione, altamente conformabile e altamente assorbente, mantiene un microambiente umido che agevola il processo di guarigione delle ferite. Facile da applicare.

Indicazioni d'uso:
- tessuto di granulazione
- ferite ipersecernenti
- ferite profonde
- ferite sanguinanti
- ferite chirurgiche deiscenti
- ulcere venose
- ulcere diabetiche
- ulcere arteriose
- siti di prelievo
- ustioni di secondo grado
- abrasioni/lacerazioni/lacerazioni cutanee
- ulcere da decubito

Controindicazioni:
- ustioni di 3° grado
- impianti cutanei

CURASORB **applicazione e rimozione/sostituzione:**
Per un'applicazione ottimale:
- irrigare la zona della ferita
- tamponare delicatamente la lesione e la zona circostante per rimuovere l'eccesso di umidità
- applicare la medicazione sulla ferita (entrambi i lati sono corretti)
- applicare la medicazione secondaria

Tecniche di rimozione:
- rimuovere la medicazione secondaria
- rimuovere la medicazione sollevandola delicatamente

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- irrigare la ferita e tamponarla
- applicare una nuova medicazione

Indicazioni per la sostituzione:
sostituire la medicazione a seconda del quantitativo di essudato. Per una ferita altamente secernente può essere necessaria anche una sostituzione giornaliera della medicazione. La medicazione può essere sostituita ogni 2-4 giorni a seconda del protocollo di lavoro seguito.

Vantaggi:
il ***CURASORB*** a base di alginati di calcio e sodio ha capacità assorbente di circa 20 volte il suo peso. La particolare tecnica di produzione definita "a puntura d'ago", permette di assorbire verticalmente dell'essudato. Si ha dunque una minimizzazione del rischio di macerazione dei tessuti perimetrali anche in presenza di elevati quantitativi di essudato.
A contatto con l'essudato della ferita ***CURASORB*** si trasforma in un foglietto gelificato ad alta consistenza grazie alla presenza di acido Guluronico. Questa caratteristica permette a ***CURASORB*** di non sfaldarsi e quindi di non provocare spargimento di frammenti durante la rimozione della medicazione e di minimizzare lo spargimento dell'essudato verso i bordi della ferita.
CURASORB risulta avere potere emostatico derivante dal contenuto di calcio in fibre, indicato quindi per ferite sanguinanti.

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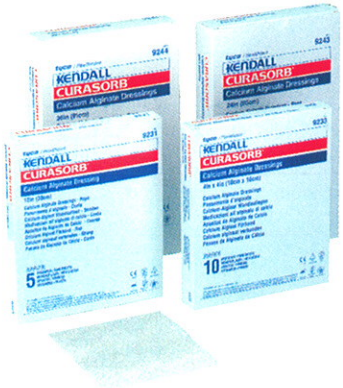
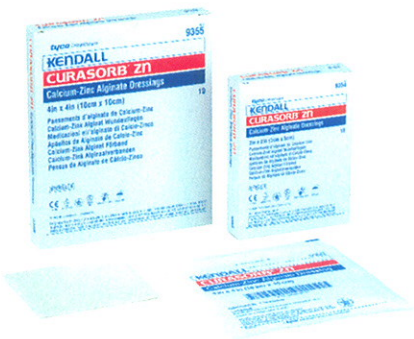
Alginati di calcio



CURASORB™

- Assorbe l'essudato proveniente dalla lesione creando un cuscino protettivo in gel e un ambiente umido ideale
- Il gel protettivo trattiene l'essudato e aiuta a prevenire la macerazione della cute
- Facile e indolore da rimuovere, minimizza il trauma tissutale e massimizza il comfort per il paziente
- Ha la capacità di assorbire circa 20 volte il suo peso
- Sterile

Codici	Descrizione	Pezzi per confezione	Pezzi per cartone
CURASORB			
9231	30 cm nastro	5	20
9232	5 x 5 cm	10	100
9233	10 x 10 cm	10	50
9236	10 x 10 cm Plus	10	50
9240	10 x 14 cm	10	50
9238	20 x 10 cm	5	50
9239	15 x 25 cm	10	50
9242	30 x 60 cm	10	50
9243	60 cm nastro	5	20
9244	90 cm nastro	5	20



CURASORB ZN™

- Medicazione di alginato di calcio con in aggiunta i benefici dello Zinco
- Il gel protettivo trattiene l'essudato e aiuta a prevenire la macerazione della cute
- Facile e indolore da rimuovere, minimizza il trauma tissutale e massimizza il comfort per il paziente
- Ha la capacità di assorbire circa 20 volte il suo peso
- Sterile

Codici	Descrizione	Pezzi per confezione	Pezzi per cartone
CURASORB ZN			
9351	30 cm nastro	5	20
9354	5 x 5 cm	10	100
9355	10 x 10 cm	10	50
9356	10 x 20 cm	5	50

Indicazioni

- Ferite da moderatamente a molto essudanti
- Ferite tunnellizzate
- Lesioni a spessore parziale e a tutto spessore
- Ulcere da pressione (stadio 2, 3 & 4)

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ALLEGATO N. 2 SCHEDA PRODOTTO

Dati per l'identificazione dei Dispositivi Medici

LOTTO NR.19

RIF 40

Codice del dispositivo secondo la **CND**__ M040402_____

(Classificazione Nazionale D.M.)

Classe di appartenenza del D.M.__IIB_____

Descrizione identificativa del D.M (adottare nella descrizione del D.M. la denominazione dell'ultimo livello CND disponibile aggiungendo qualsiasi caratteristica atta ad individuare il D.M. es: forma, mono-pluriuso, sterile-non sterile, materiale e dimensioni. Se trattasi di Kit o sistemi specificare i componenti) _ MEDICAZIONI IN ALGINATO - MEDICAZIONE DI ALGINATO DI CALCIO 20X10 CM_____

Nome commerciale e Modello (presente in etichetta)__CURASORB_____

Denominazione Fornitore___TYCO HEALTHCARE ITALIA S.P.A._____

Codice DM. Fornitore_____9238_____

Denominazione Fabbricante (potrebbe coincidere con il Fornitore)___ TYCO HEALTHCARE GROUP LP - MANSFIELD USA_____

Nome commerciale e Modello (generalmente presente in etichetta)___ CURASORB _____

Codice D.M Fabbricante_____9238_____

Unità di misura minima_____1 PEZZO_____

(si intende il DM minimo utilizzabile)

Confezione minima di vendita___10 SCATOLE DA 5 PEZZI_____

(si intende la confezione minima e/o multipli di essa ordinabili)

Destinazione d'uso secondo certificazione CE____GESTIONE LOCALE DELLE FERITE ESTERNE COME PER ESEMPIO ULCERE DA STASI DA PRESSIONE ULCERE ARTERIOSE ULCERE DIABETICHE O LESIONI SIMILI CHE SI MANIFESTANO CON SOLUZIONE DI CONTINUO A CARICO DEL DERMA SOLO CON INTENTO SECONDARIO

Descrizione dei materiali costituenti il D.M , se di origine animale specificare la provenienza

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_____ALGINATO DI CALCIO E SODIO A BASE DI ACIDO GULURONICO 68% ACIDO MANNURONICO 32% IN MATERIALE NATURALE, PERCENTUALE DI IMPUREZZE INFERIORE AL 2% E PH 6,5

Specificare se Latex-Free_____SI_____

Indicazione del tipo di sterilizzazione__RAGGI GAMMA_____

Condizioni specifiche di conservazione e manipolazione ove previsto

_____

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Amministratore

U 7 SET. 2007

ALLEGATO N. 3

SCHEDA FORNITORE

LOTTO NR. 19

Fornitore X Produttore ☐

RAGIONE SOCIALE :
…Tyco Healthcare Italia S.p.A……..

SEDE AMMINISTRATIVA : VIALE RIVOLTANA 2/D- 20090 SEGRATE (MI)……

TELEFONO : ……02/703171…….. **FAX :** ……02/70308006……

REFERENTE E N. TELEFONICO
A CUI RICHIEDERE EVENTUALI INFORMAZIONI DI CARATTERE TECNICO SUL PRODOTTO
……SPECIALISTA DI PRODOTTO SIG.RA PATRIZIA NAPOLITANO CELL. 335/8415932
……PROMOTORI DI ZONA SIG. CRISTIAN SILIGARDI CELL 335/6385390
… SIG.RA ROBERTA COLLINI CELL 335/5744620
……

AREA DI VENDITA

Deposito presso cui devono essere inviate Richieste di consegna: …
Tyco Healthcare Italia S.p.A. CUSTOMER SERVICE - VIA RIVOLTANA 2/D – 20090 SEGRATE (MI) – TEL 02/703171 – FAX 02/7530125 ……

Presenza dell'informatore tecnico - scientifico SI X NO ☐

Se si, indicare:
Nome e Cognome ……
N. Telefonico……
SPECIALISTA DI PRODOTTO SIG.RA PATRIZIA NAPOLITANO CELL. 335/8415932
……PROMOTORI DI ZONA SIG. CRISTIAN SILIGARDI CELL 335/6385390
… SIG.RA ROBERTA COLLINI CELL 335/5744620

Firma

tyco Healthcare Italia SpA
CRISTINA DENARO
Amministratore

07 SET. 2007

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Via Rivoltana, 2/D
20090 Segrate (MI)

Tel. +39 02 70317.1
Fax +39 02 70317317
www.tycohealthcare.it

Cap. Soc. Euro 258.500
R.E.A. di Milano N. 1234987
C.F.-P. Iva - Iscr. Reg. Impr. MI 08641790152

Segrate, 07/09/2007
Ns. prot. 76390/07/EVIL

Spettabile
AGENZIA REGIONALE PER L' ACQUISTO
VIA ALDO MORO, 38
40127 BOLOGNA (BO)

Oggetto: **GARA PER LA FORNITURA DI MATERIALE DA MEDICAZIONE AVANZATA E SPECIALE**

LOTTO NR.19

La sottoscritta Tyco Healthcare Italia S.p.A. - Sede Legale ed Amministrativa in Via Rivoltana, 2/D - 20090 Segrate (MI) - Tel.: 02/70317.1 - Fax: 02/70308006 - Capitale Sociale euro 258.500,00# - Codice Fiscale / Partita IVA / Iscrizione Registro Imprese della C.C.I.A.A. di Milano n. 08641790152 - Iscritta alla R.E.A. della C.C.I.A.A. di Milano al n. 1234987, nella persona di un suo Amministratore, Sig.ra Cristina Denaro, nata a Menfi (AG) il 24/04/1964, C.F. DNRCST64D64F126U, residente in Piazza Kennedy n. 1, 40033 Casalecchio di Reno (BO), in seguito a quanto specificato in oggetto,

Ai sensi e per gli effetti di quanto previsto dall'art. 13 D.Lvo 163/06

D I C H I A R A

- che, nell'ambito dell'offerta e delle giustificazioni poste a base della medesima, non sono presenti informazioni che costituiscano segreti tecnici o commerciali o coperte da riservatezza, ***ad eccezione delle giustificazioni relative alle voci di prezzo presentate insieme alle offerte economiche***.

Resta a disposizione per eventuali chiarimenti o necessità e con l'occasione porge distinti saluti.

Tyco Healthcare Italia S.p.A.
Cristina Denaro
(Amministratore)

TYCO Healthcare Italia S.p.A.
Via Rivoltana, 2/D
20090 Segrate (MI)

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Ns. prot. 76390/07/EVIL

Spettabile
AGENZIA REGIONALE PER L' ACQUISTO
VIA ALDO MORO, 38
40127 BOLOGNA (BO)

Oggetto: **GARA PER LA FORNITURA DI MATERIALE DA MEDICAZIONE AVANZATA E SPECIALE**

LOTTO NR. 19

La sottoscritta Tyco Healthcare Italia S.p.A. - Sede Legale ed Amministrativa in Via Rivoltana, 2/D - 20090 Segrate (MI) - Tel.: 02/70317.1 - Fax: 02/70308006 - Capitale Sociale euro 258.500,00# - Codice Fiscale / Partita IVA / Iscrizione Registro Imprese della C.C.I.A.A. di Milano n. 08641790152 - Iscritta alla R.E.A. della C.C.I.A.A. di Milano al n. 1234987, nella persona di un suo Amministratore, Sig.ra Cristina Denaro, nata a Menfi (AG) il 24/04/1964, C.F. DNRCST64D64F126U, residente in Piazza Kennedy n. 1, 40033 Casalecchio di Reno (BO), in seguito a quanto specificato in oggetto,

D I C H I A R A

- che i prodotti offerti riportano il Marchio CE e sono conformi a quanto previsto dalla direttiva CEE N. 93/42/EEC vigente in materia, D.L. 24/02/97 N. 46 Dispositivi Medici
- che i prodotti offerti rispondono a quanto previsto dalla normativa vigente in tema di etichettatura e confezionamento.

Resta a disposizione per eventuali chiarimenti o necessità e con l'occasione porge distinti saluti.

Tyco Healthcare Italia S.p.A.
Cristina Denaro
(Amministratore)

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Healthcare

Kendall

DECLARATION OF CONFORMITY

15 Hampshire Street
Mansfield, MA 02048
Tel: 508-261-8000
Fax: 508-261-8461
www.kendallhq.com

Technical File: SDG-40

The undersigned declares that the products named and listed on this certificate meet the provisions of the European Communities Council Directive 93/42/EEC and the Essential Principles and classification rules according to Scedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002, which apply to them and the CE mark may be affixed.

General Product Name	Advanced Wound Care Dressings
Manufacturer:	Kendall, a division of Tyco Healthcare Group LP 15 Hampshire Street Mansfield, MA 02048 USA
EC Representative:	Tyco Healthcare Group UK Ltd. 154 Fareham Road Gosport, Hampshire PO13 0AS UK
Intended Use:	The Class IIa devices in this file are used as protective dressings for various types of draining and non-draining wounds. Some dressings may also be used for moderate to heavy exudating wounds due to their absorptive properties. The Class IIb devices in this file are used in the local management of external wounds such as venous stasis, pressure, arterial and diabetic ulcers or similar type wounds which have breached the dermis and can only heal by secondary intent.
Sterility:	Yes Refer to Attached Table
Measuring Function:	No
Directive Classification:	IIa and IIb
In Accordance with Annex:	II
Corresponding Australian Clause:	1.8, Schedule 3
Reorder Codes/GMDN Code	Refer to Attached Table
Date Approved for CE Marking:	Refer to Attached Table
Current Standards to which Conformity is declared:	Refer to Attached Table
Notified Body:	TUV Product Services GMBH Number: CE# 0123
EC Certificate(s)	G1 05 11 17679 092 expires 23-Feb-10 G105 11 17679 089 expires 14-Sep-10

Signed by: Debora Stapleton
Debora Stapleton, Sr. Reg Affairs Specialist

07/17/2006
Date

SDG-40
Rev. 07 17-Jul-06

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Amministratore

tyco
Healthcare

Kendall

15 Hampshire Street
Mansfield, MA 02048
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Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	MDD Rule	GMDN Code	Date Approved for CE
Class IIa		*Annex II*			
16933	HydraFoam Wound Dressings 3" x 3"	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001
16944	HydraFoam Wound Dressings 4" x 4"	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001
16948	HydraFoam Wound Dressings 4" x 8"	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001
16966	HydraFoam Wound Dressings 6" x 6"	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001
16988	HydraFoam Wound Dressings 8" x 8"	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001
3335	Curasalt Packing Strips 1/2" x 5 yards	Gamma	4	Dressing/wound saline solution [37298]	3/15/2001
3339	Curasalt Sodium Chloride Dressing	Steam	4	Dressing/wound saline solution [37298]	3/15/2001
6111	Curity Non-Adherent, Oil Emulsion Dressing 1/2" x 4 yds	Gamma	4	Dressing, nonadherent [11325]	3/15/2001

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Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	MDD Rule	GMDN Code	Date Approved for CE
6112	Curity Non-Adherent, Oil Emulsion Dressing 3" x 3"	Gamma	4	Dressing, nonadherent [11325]	3/15/2001
6113	Curity Non-Adherent, Oil Emulsion Dressing 3" x 8"	Gamma	4	Dressing, nonadherent [11325]	3/15/2001
6114	Curity Non-Adherent, Oil Emulsion Dressing 3" x 16"	Gamma	4	Dressing, nonadherent [11325]	3/15/2001
6115	Curity Non-Adherent, Oil Emulsion Dressing 3" x 8" 3/pk	Gamma	4	Dressing, nonadherent [11325]	3/15/2001
6116	Curity Non-Adherent, Oil Emulsion Dressing 5" x 9"	Gamma	4	Dressing, nonadherent [11325]	3/15/2001
6121	Curity Non-Adherent, Oil Emulsion Dressing 9" x 18"	Gamma	4	Dressing, nonadherent [11325]	3/15/2001
6640	Polyskin II 2" x 2.75"	EO	4	Dressing, transparent adhesive [17428]	5/24/2000
6641	Polyskin II 4" x 4.75"	EO	4	Dressing, transparent adhesive [17428]	5/24/2000
6642	Polyskin II 6" x 8"	EO	4	Dressing, transparent adhesive [17428]	5/24/2000

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Healthcare Italia SpA
CRISTINA BENARIO
Amministratore

tyco
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Kendall

15 Hampshire Street
Mansfield, MA 02048
Tel: 508-261-8000
Fax: 508-261-8461
www.kendallhq.com

Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	MDD Rule	GMDN Code	Date Approved for CE
6647	Polyskin II 4" x 8"	EO	4	Dressing, transparent adhesive [17428]	5/24/2000
6648	Polyskin II 8" x 10"	EO	4	Dressing, transparent adhesive [17428]	5/24/2000
6651	Polyskin II 1-1/2" x 1-1/2"	EO	4	Dressing, transparent adhesive [17428]	5/24/2000
6652	Polyskin MR Transparent Dressing 2" x 2-3/4"	EO	4	Dressing, transparent adhesive [17428]	5/24/2000
6654	Polyskin MR Transparent Dressing 4" x 4-3/4"	EO	4	Dressing, transparent adhesive [17428]	5/24/2000
6655	Polyskin MR Transparent Dressing 6" x 8"	EO	4	Dressing, transparent adhesive [17428]	5/24/2000
8884472005	Viasorb Dressing 6" x 10"	EO	4	Dressing, nonadherent [11325]	12/19/1999
8884472104	Viasorb Dressing 3" x 10 yards	EO	4	Dressing, nonadherent [11325]	12/19/1999

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www.kendallhq.com

Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	MDD Rule	GMDN Code	Date Approved for CE
8884472401	Viasorb Dressing 4" x 6"	EO	4	Dressing, nonadherent [11325]	12/19/1999
8884472500	Viasorb Dressing 7" x 7"	EO	4	Dressing, nonadherent [11325]	12/19/1999
8884472641	Viasorb Dressing 2" x 3"	EO	4	Dressing, nonadherent [11325]	12/19/1999
8884474001	Blisterfilm 2" x 3"	EO	4	Dressing, transparent adhesive [17428]	12/19/1999
8884474019	Blisterfilm 3-1/2" x 4"	EO	4	Dressing, transparent adhesive [17428]	12/19/1999
8884474027	Blisterfilm 5-1/2" x 6"	EO	4	Dressing, transparent adhesive [17428]	12/19/1999
8884474035	Blisterfilm 4" x 5"	EO	4	Dressing, transparent adhesive [17428]	12/19/1999
8886834000	Owens Dressings 3" x 3"	Gamma	4	Dressing, nonadherent [11325]	12/19/1999
8886834100	Owens Dressings 3" x 8"	Gamma	4	Dressing, nonadherent [11325]	12/19/1999

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Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	MDD Rule	GMDN Code	Date Approved for CE
8886834200	Owens Dressings 8" x 12"	Gamma	4	Dressing, nonadherent [11325]	12/19/1999
Class IIb		*Annex II*			
55522	COPA Foam Dressing 2 x 2	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	01/17/06
55522P	COPA Plus Foam 2 x 2	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	1/17/06
55533	COPA Foam Dressing 3 x 3	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	01/17/06
55533P	COPA Plus Foam 3 x 3	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	1/17/06
55535	COPA Fenestrated 3.5 x 3	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	1/17/06
55535P	COPA Plus Fenestrated 3.5 x 3	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	1/17/06
55544	COPA Foam Dressing 4 x 4	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	01/17/06

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Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	MDD Rule	GMDN Code	Date Approved for CE
55544B	COPA Island Foam 4 x 4-2 x 2 PD SZ	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	1/17/06
55544P	COPA Plus Foam 4 x 4	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	1/17/06
55548	COPA Foam Dressing 4 x 8	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	1/17/06
55548P	COPA Plus Foam 4 x 8	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	1/17/06
55555	COPA Foam Dressing 5 x 5	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	1/17/06
55555P	COPA Plus Foam 5 x 5	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	1/17/06
55566	COPA Foam Dressing 6 x6	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	1/17/06
55566B	COPA Island Foam 6 x 6-4 x 4 PD SZ	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	1/17/06
55566P	COPA Plus Foam 6 x 6	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	1/17/06

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Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	MDD Rule	GMDN Code	Date Approved for CE
55588	COPA Foam Dressing 8 x 8	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	1/17/06
55588B	COPA Island Foam 8 x 8-6 x 6 PD SZ	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	1/17/06
55588P	COPA Plus Foam 8 x 8	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	1/17/06
9080	Curafoam Plus Dressing 2 x 2 in.	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	6/23/2000
9081	Curafoam Plus Dressing 4 x 4 in.	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	6/23/2000
9082	Curafoam Plus Dressing 4 x 5 in.	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	6/23/2000
9083	Curafoam Plus Dressing 4 x 8 in.	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	6/23/2000
9084	Curafoam Plus Dressing 6 x 6 in.	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	6/23/2000

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Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	MDD Rule	GMDN Code	Date Approved for CE
9085	Curafoam Plus Dressing 8 x 8 in.	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	6/23/2000
9090	Curafoam Island 2 x 2 Pad	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	6/23/2000
9091	Curafoam Island 3.5 x 3.5 in. Pad	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	6/23/2000
9092	Curafoam Island 5.5 x 5.5 in. Pad	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	6/23/2000
9231	Curasorb Calcium Alginate Dressing, 12" Rope	Gamma	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001
9232	Curasorb Calcium Alginate Dressing, 2" x2"	Gamma	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001
9233	Curasorb Calcium Alginate Dressing, 4" x4"	Gamma	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001
9236	Curasorb Plus Calcium Alginate Dressing, 4" x4"	Gamma	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001
9238	Curasorb Calcium Alginate Dressing, 8" x4"	Gamma	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001

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Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	MDD Rule	GMDN Code	Date Approved for CE
9239	Curasorb Calcium Alginate Dressing, 6" x10"	Gamma	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001
9240	Curasorb Calcium Alginate Dressing, 4" x 5.5"	Gamma	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001
9242	Curasorb Calcium Alginate Dressing, 12" x 24"	Gamma	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001
9243	Curasorb Calcium Alginate Dressing, 24" Rope	Gamma	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001
9244	Curasorb Calcium Alginate Dressing, 36" Rope	Gamma	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001
9351	Curasorb Zinc 12" Rope	Gamma	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001
9354	Curasorb Zinc 2" x 2"	Gamma	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001
9355	Curasorb Zinc 4" x 4"	Gamma	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001

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Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	MDD Rule	GMDN Code	Date Approved for CE
9356	Curasorb Zinc 4" x 8"	Gamma	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	3/15/2001
9390	Curafoam Foam Dressing 2 x 2 in.	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	6/23/2000
9391	Curafoam Foam Dressing 4 x 4 in.	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	6/23/2000
9392	Curafoam Foam Dressing 4 x 4 in. sponge	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	6/23/2000
9393	Curafoam Foam Dressing 8 x 4 in.	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	6/23/2000
9394	Curafoam Foam Dressing 6 x 8 in.	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	6/23/2000
9395	Curafoam Foam Dressing 8 x 10 in.	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	6/23/2000
9396	Curafoam Foam Dressing 4 x 5 in.	EO	4	Dressing, high-absorbent, foam/sheet/liquid/powder [43186]	6/23/2000

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Standards to Which Conformitry is Declared

Standard	Standard Title	Version
93/42/EEC	Council Directive 93/42/EEC Of 14 June 1993 Concerning Medical Devices	1993
EN 550	Sterilization Of Medical Devices - Validation And Routine Control Of Ethylene Oxide Sterilization	1994
EN 552	Sterilization Of Medical Devices - Validation And Routine Control Of Sterilization By Irradiation	94 AMD 2 2000
EN 554	Sterilization Of Medical Devices - Validation And Routine Control Of Sterilization By Moist Heat	1994
ISO 11137	Sterilization Of Heath Care Products – Requirements For Validation And Routine Control – Radiation Sterilization	1995 AMD 1 2001
ISO 11135	Medical Devices – Validation And Routine Control Of Ethylene Oxide Sterilization	1994 COR 1 1994
ISO 11134	Sterilization Of Health Care Products – Requirements For Validation And Routine Control – Industrial Moist Heat Sterilization	1 ED 1994
ISO 10993-1	Biological Evaluation Of Medical Devices – Evaluation And Testing	3 ED 2003
ISO 13485:1996	Quality Systems- Medical Devices – Particular Requirements For The Application Of ISO 9001	1996
ISO 14971	Medical Devices – Application Of Risk Management To Medical Devices	2000 AMD 1 2003

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Standards to Which Conformitry is Declared

Standard	Standard Title	Version
ISO 13485:2003	Quality Systems - Medical Devices - Particular Requirements For The Application Of ISO 9001	2003

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DECLARATION OF CONFORMITY

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Technical File: SDG-45

The undersigned declares that the products named and listed on this certificate meet the provisions of the European Communities Council Directive 93/42/EEC and the Essential Principles and classification rules according to Scedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002, which apply to them and the CE mark may be affixed.

General Product Name	**Ultec Pro Alginate Hydrocolloid Wound Dressings**
Manufacturer:	**Kendall, a division of Tyco Healthcare Group LP** **15 Hampshire Street** **Mansfield, MA 02048 USA**
EC Representative:	**Tyco Healthcare Group UK Ltd.** **154 Fareham Road** **Gosport, Hampshire PO13 0AS UK**
Intended Use:	**Ultec Pro Alginate Hydrocolloid Dressings are intended for use on partial thickness or shallow full thickness wounds that are heavily exudating.**

Sterility:	**Yes** **Refer to Attached Table**
Measuring Function:	**No**
Directive Classification:	**IIb**
In Accordance with Annex:	**II**
Corresponding Australian Clause:	**1.8, Schedule 3**
Reorder Codes/GMDN Code	**Refer to Attached Table**
Date Approved for CE Marking:	**Refer to Attached Table**
Current Standards to which Conformity is declared:	**Refer to Attached Table**
Notified Body:	**TUV Product Services GMBH** Number: **CE# 0123**
EC Certificate(s)	**G105 11 17679 089 expires 14-Sep-10**

Signed by: Debora Stapleton

Debora Stapleton, Sr. Reg Affairs Specialist

05/03/06
Date

SDG-45
Rev. 05 03-May-06

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Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	MDD Rule	GMDN Code	Date Approved for CE
Class IIb		*Annex II*			
9801	Ultec Pro Alginate Hydrocolloid Dressing, 4" x 4"	Gamma	4	Dressing, skin graft, donor-site [15319]	3/15/2001
9802	Ultec Pro Alginate Hydrocolloid Dressing, 6" x 6"	Gamma	4	Dressing, skin graft, donor-site [15319]	3/15/2001
9804	Ultec Pro Alginate Hydrocolloid Dressing, 8" x 8"	Gamma	4	Dressing, skin graft, donor-site [15319]	3/15/2001
9805	Ultec Pro Alginate Hydrocolloid Dressing, 4" x 5" Sacral	Gamma	4	Dressing, skin graft, donor-site [15319]	3/15/2001
9806	Ultec Pro Alginate Hydrocolloid Dressing, 6" x 7" Sacral	Gamma	4	Dressing, skin graft, donor-site [15319]	3/15/2001
9807	Ultec Pro Border Alginate Hydrocolloid Dressing, 2.5" x 2.5"	Gamma	4	Dressing, skin graft, donor-site [15319]	3/15/2001
9808	Ultec Pro Border Alginate Hydrocolloid Dressing, 4" x 4"	Gamma	4	Dressing, skin graft, donor-site [15319]	3/15/2001
9809	Ultec Pro Border Alginate Hydrocolloid Dressing, 6" x 6"	Gamma	4	Dressing, skin graft, donor-site [15319]	3/15/2001

Technical File: SDG-45

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Standards to Which Conformitry is Declared

Standard	Standard Title	Version
93/42/EEC	Council Directive 93/42/EEC Of 14 June 1993 Concerning Medical Devices	1993
ISO 9002	Quality Systems – Model For Quality Assurance In Production And Installation	2 ED 1994
EN 552	Sterilization Of Medical Devices - Validation And Routine Control Of Sterilization By Irradiation	94 AMD 2 2000
EN 980	Graphical Symbols For Use In The Labelling Of Medical Devices	2003
ISO 9001	Quality Management System Requirements	1994
ISO 13485:2003	Quality Systems - Medical Devices - Particular Requirements For The Application Of ISO 9001	2003
ISO 10993-1	Biological Evaluation Of Medical Devices – Evaluation And Testing	3 ED 2003
ISO 14971	Medical Devices – Application Of Risk Management To Medical Devices	2000 AMD 1 2003
ISO 11137	Sterilization Of Heath Care Products – Requirements For Validation And Routine Control – Radiation Sterilization	1995 AMD 1 2001
EN 556-1	Sterilization Of Medical Devices - Requirements For Medical Devices To Be Designated "Sterile" - Part 1: Requirements For Terminally Sterilized Medical Devices	2001

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Standards to Which Conformitry is Declared

Standard	Standard Title	Version
ISO 13485:1996	Quality Systems- Medical Devices – Particular Requirements For The Application Of ISO 9001	1996

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DECLARATION OF CONFORMITY

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Technical File: SDG-46

The undersigned declares that the products named and listed on this certificate meet the provisions of the European Communities Council Directive 93/42/EEC and the Essential Principles and classification rules according to Scedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002, which apply to them and the CE mark may be affixed.

General Product Name	**Hydrogel Wound Dressings**
Manufacturer:	**Kendall, a division of Tyco Healthcare Group LP** **15 Hampshire Street** **Mansfield, MA 02048 USA**
EC Representative:	**Tyco Healthcare Group UK Ltd.** **154 Fareham Road** **Gosport, Hampshire PO13 0AS UK**
Intended Use:	**Hydrogel wound dressings are used on intact and abraded skin and on wounds to protect against external contamination and to prevent dehydration. Hydrogel dressings are also highly absorptive and are used to absorb excess wound exudate. AquaFlo, Curafil and Curagel are used on various wounds, while MotherMates are a variant of AquaFlo shaped to fit over the nipple of lactating mothers.**
Sterility:	**Yes and No Refer to Attached Table**
Measuring Function:	**No**
Directive Classification:	**IIa and IIb**
In Accordance with Annex:	**II**
Corresponding Australian Clause:	**1.8, Schedule 3**
Reorder Codes/GMDN Code	**Refer to Attached Table**
Date Approved for CE Marking:	**Refer to Attached Table**
Current Standards to which Conformity is declared:	**Refer to Attached Table**
Notified Body:	**TUV Product Services GMBH Number: CE# 0123**
EC Certificate(s)	**G1 05 11 17679 092 expires 23-Feb-10** **G105 11 17679 089 expires 14-Sep-10**

Signed by: Debora Stapleton
Debora Stapleton, Sr. Reg Affairs Specialist

05/04/06
Date

SDG-46
Rev. 06 04-May-06

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Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	MDD Rule	GMDN Code	Date Approved for CE
Class IIa		*Annex II*			
8884476105	Aquaflo Hydrogel 1.5" disc	Gamma	4	Dressing, occlusive, hydrogel [34082]	2/9/2000
8884476139	Aquaflo Hydrogel 3" disc	Gamma	4	Dressing, occlusive, hydrogel [34082]	2/9/2000
8884476154	Aquaflo Hydrogel 4.75" disc	Gamma	4	Dressing, occlusive, hydrogel [34082]	2/9/2000
9403	Mothermates Hydrogel 3"	Gamma	4	Dressing, occlusive, hydrogel [34082]	9/19/2001
9403B	Mothermates Hydrogel 3" Bulk	Gamma	4	Dressing, occlusive, hydrogel [34082]	9/5/2002
9404	Mothermates Hydrogel 3" Retail	Gamma	4	Dressing, occlusive, hydrogel [34082]	9/5/2002
9408	Mothermates Hydrogel 3" Intl.	Gamma	4	Dressing, occlusive, hydrogel [34082]	1/14/2003
9900	Curagel Hydrogel 2"x 3"	Gamma	4	Dressing, occlusive, hydrogel [34082]	10/1/2001

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Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	MDD Rule	GMDN Code	Date Approved for CE
9901	Curagel Hydrogel 4"x 4"	Gamma	4	Dressing, occlusive, hydrogel [34082]	10/21/2000
9902	Curagel Hydrogel 8"x 8"	Gamma	4	Dressing, occlusive, hydrogel [34082]	10/21/2000
9903	Curagel Hydrogel Island 3"x 4"	Gamma	4	Dressing, occlusive, hydrogel [34082]	10/21/2000
9904	Curagel Hydrogel Island 5"x 5"	Gamma	4	Dressing, occlusive, hydrogel [34082]	10/21/2000
9905	Curagel Hydrogel 8.5"x 9.5"	Gamma	4	Dressing, occlusive, hydrogel [34082]	10/21/2000
Class IIb		*Annex II*			
9250	Curafil Gel ½ oz tube	Non	4	Dressing, occlusive, hydrogel [34082]	2/9/2000
9251	Curafil Gel 1 oz tube	Non	4	Dressing, occlusive, hydrogel [34082]	2/9/2000
9252	Curafil Gel 3 oz tube	Non	4	Dressing, occlusive, hydrogel [34082]	2/9/2000

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Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	MDD Rule	GMDN Code	Date Approved for CE
9255	Curafil Gauze 2"x 2"	Gamma	4	Dressing, occlusive, hydrogel [34082]	10/21/2000
9256	Curafil Gauze 4"x 4"	Gamma	4	Dressing, occlusive, hydrogel [34082]	10/21/2000
9257	Curafil Gauze 8"x 4"	Gamma	4	Dressing, occlusive, hydrogel [34082]	10/21/2000
9259	Curafil Packing Strip 1" x 36"	Gamma	4	Dressing, occlusive, hydrogel [34082]	10/21/2000

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Standards to Which Conformitry is Declared

Standard	Standard Title	Version
93/42/EEC	Council Directive 93/42/EEC Of 14 June 1993 Concerning Medical Devices	1993
ISO 9001	Quality Management System Requirements	1994
EN 552	Sterilization Of Medical Devices - Validation And Routine Control Of Sterilization By Irradiation	94 AMD 2 2000
80/181/EEC	Council Directive on the Approximation of the Laws of the Member States Relating to Units of Measurement	2001
ISO 14971	Medical Devices – Application Of Risk Management To Medical Devices	2000 AMD 1 2003
EN 1041	Information Supplied By The Manufacturer With Medical Devices	1998
EN 12442-1	Animal Tissues And Their Derivatives Utilized In The Manufacture Of Medical Devices - Part 1: Analysis And Management Of Risk	2000
EN 13726-1	Test Methods for Primary Wound Dressings — Part 1: Aspects of Absorbency	2002
ISO 11137	Sterilization Of Heath Care Products – Requirements For Validation And Routine Control – Radiation Sterilization	1995 AMD 1 2001
EN 868-1	Packaging Materials And Systems For Medical Devices Which Are To Be Sterilized - General Requirements And Test Methods	1997

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Standards to Which Conformitry Is Declared

Standard	Standard Title	Version
ISO 13485:1996	Quality Systems- Medical Devices – Particular Requirements For The Application Of ISO 9001	1996
EN 980	Graphical Symbols For Use In The Labelling Of Medical Devices	2003
EN 550	Sterilization Of Medical Devices - Validation And Routine Control Of Ethylene Oxide Sterilization	1994
ISO 13485:2003	Quality Systems - Medical Devices - Particular Requirements For The Application Of ISO 9001	2003

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service

EC-CERTIFICATE

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 05 11 17679 092

Manufacturer:	Kendall, a division of Tyco Healthcare Group LP 15 Hampshire Street Mansfield MA 02048 USA
EC-Representative:	Tyco Healthcare UK LTD. 154 Fareham Road Gosport, PO13 OAS UNITED KINGDOM
Product Category(ies):	Medical Devices for Wound Care and Closure, Cardio-Thoracic, Respiratory / Anesthesia, Suction / Aspiration, Blood Collection, Gastro-Intestinal Management, Urology, Dialysis / Vascular Access, Enteral Feeding, Needles and Syringes, Thermometry, Intravascular Cardiology and other Related Therapies, as specified in the attachment to this certificate

The Certification Body of TÜV Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

Report No.: DM404220

Valid until: 2010-02-23

Date, 2005-12-22

Reiner Krumme

TÜV 217903

TÜV Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

TÜV Product Service GmbH · TÜV SÜD Gruppe · Zertifizierstelle · Ridlerstrasse 65 · 80339 München · Germany

07 SET. 2007

CRISTINA DENARO
Amministratore

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service

EC-Certificate
Full Quality Assurance System
(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)
No. G1 05 11 17679 092

Facility(ies):

Kendall, a division of Tyco Healthcare Group LP
15 Hampshire Street, Mansfield MA 02048, USA

Kendall, a division of Tyco Healthcare Group LP
2010 Internat. Speedway Blvd., Deland FL
32721-2078, USA

Kendall, a division of Tyco Healthcare Group LP
400 Maple Street, Commerce TX 75428, USA

Kendall, a division of Tyco Healthcare Group LP
1222 Sherwood Road, Norfolk NE 68701, USA

Kendall, a division of Tyco Healthcare Group LP
130 South Main Street, Oriskany Falls NY 13425,
USA

Kendall, a division of Tyco Healthcare Group LP
98.6 Faichney Drive, Watertown NY 13601, USA

Nellcor Puritan Bennett Mexico S.A. de C.V.
Boulevard Insurgentes #37, 22570 Tijuana, B.C.,
MEXICO

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Tyco Italia SpA
CRISTINA DEMARO
Amministratore

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Attachment for Certificate No. G1 05 11 17679 092
Dated 2005-11- 05

Facilities and Products Included:

Commerce, TX 75428 USA (Manufacturing Only) - 36967

Intravascular Access Devices
- Hypodermic Syringes
- Hypodermic Needles

Suction Aspiration / Devices
- Tubing Connectors
- Perfusion Adaptors

Deland, FL 32724 USA (Manufacturing Only) - 36964

Blood Collection Devices
- Blood Collection Needles
- Blood Collection Lancets

Intravascular Access Devices
- Hypodermic Syringes
- Hypodermic Needles
- Spinal and Epidural Anesthesia Needles
- Bone Marrow/Biopsy Needles
- Dental Needles

Norfolk, NE 68701 USA (Manufacturing Only) - 38170

Intravascular Access Devices
- Hypodermic Syringes
- Hypodermic Needles

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Amministratore

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TÜV SÜD
Product Service

Attachment for Certificate No. G1 05 11 17679 092
Dated 2005-11- 05

Facilities and Products Included:

Oriskany Falls, NY 13425 USA (Manufacturing Only) - 36963

Wound Care Devices
- Synthetic Wound Dressings
- Impregnated Wound Dressings

Enteral Feeding/Gastrointestinal Tract Devices
- Gastrostomy Tubes and P.E.G. Tubes

Dialysis / Vascular Access Devices
- Irrigation Syringes

Watertown, NY 13601 USA (Manufacturing Only) - 35941

Thermometry Devices
- Electronic Predictive Thermometers & Accessories
- Electronic Tympanic Thermometers & Accessories

Cardio-Thoracic Devices
- Auto-Transfusion Chest Drainage Devices

Enteral Feeding / Gastrointestinal Tract Devices
- Enteral Infusion Pumps

Vascular Compression Devices
- Sequential Compression Device Controller

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Tyco Healthcare Italia SpA
CRISTINA DENARO
Amministratore

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TÜV SÜD Product Service

Attachment for Certificate No. G1 05 11 17679 092
Dated 2005-11- 05

Facilities and Products Included:

Nellcor Puritan Bennett Mexico, S.A. de C.V.
La Mesa, Tijuna, B.C. Mexico (Manufacturing Only) - 49898

Cardio-Thoracic Devices
- Cardiovascular Shunts
- Thoracic Drainage Catheters
- Thoracentesis & Pneumothorax Devices
- Nasal Cannula / Gas Detector

Enteral Feeding/Gastrointestinal Tract Devices
- Enteral Pump Administration Sets
- Stomach Decompression & Drainage Tubes
- Nasogastric Feeding Tubes

Urological Drainage Devices
- Indwelling Urinary Drainage Catheters

Suction Aspiration Devices
- Surgical Site Suction Tubes

Intravascular Access Devices
- Vascular Tapes

Wound Care Devices
- Dressings

Blood Collection Devices
- Blood Collection Needles
- Blood Collection Lancets
- Fluid Transfer Sets

Munich, CRT-2

Reiner Krumme

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CRISTINA DENARO
Amministratore

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC-CERTIFICATE

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 05 11 17679 089

Manufacturer:	Kendall, a division of Tyco Healthcare Group LP 15 Hampshire Street Mansfield MA 02048 USA
EC-Representative:	Tyco Healthcare UK LTD. 154 Fareham Road Gosport, PO13 OAS UNITED KINGDOM
Product Category(ies):	Synthetic Wound Dressings

The Certification Body of TÜV Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

Report No.: DM404220

Valid until: 2010-09-14

217915

Date, 2005-12-22

Reiner Krumme

TÜV Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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CRISTINA DENARO
Amministratore

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC-Certificate
Full Quality Assurance System
(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)
No. G1 05 11 17679 089

Facility(ies):

Kendall, a division of Tyco Healthcare Group LP
15 Hampshire Street, Mansfield MA 02048, USA

Kendall, a division of Tyco Healthcare Group LP
1430 Marvin Griffin Road, Augusta GA 30913, USA

TÜV Product Service GmbH
TÜV SÜD Gruppe · Zertifizierstelle
Ridlerstr. 65 · 80339 München
Germany

Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-999-98712-46

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CRISTINA DENARO
Amministratore

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СВИДЕТЕЛЬСТВО ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD America

CERTIFICATE

The Certification Body of
TÜV AMERICA INC.
Management Service Division

hereby certifies that

Kendall
A Division of Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048 USA

has implemented a Quality Management System
in accordance with:

ISO 13485:2003

The scope of this Quality Management System includes:

Design, Manufacture, Distribution and Servicing of Sterile and Non-Sterile Medical Devices and Kits, Including: Airway Management/Diagnostics; Biomedical Electrodes, Cables and Lead Wires; Blood and Specimen Collection; Blood Bags Cardio-Thoracic Catheters and Drainage; Cardio-Vascular Shunts (Coated and Uncoated) and Catheters; Compression Stockings; Dialysis Catheters, Guide Wires and Related Accessories; Enteral Feeding and Access; Filled Syringes (Water and Lubricant); Hot and Cold Packs, Hydrogel Membranes, Incontinence/Maternity Care; Intravascular Access; Irrigation Trays and Solutions; Medical Recording Charts; Needles, Lancets and Syringes (With and Without Needles); O.R./Surgical Suction; Operating Room Support Products; Respiratory; SCD Vascular Therapy Pump, Sleeves and Related Accessories; Sharps Disposal; Suction and G.I. Management; Thermometry and Related Accessories; Urological Meters, Catheters (Coated and Uncoated) and Drain Bags; Vascular Catheters; Wound Care.

This Certificate is valid until: January 20, 2009

Certificate Registration No: S 951 03 1670

Issued: March 20, 2003
Revised: May 23, 2006

TÜV SÜD

Gary W. Minks
Director, Certification Body

SCC Accredited CB-MS
OCSM Accrédité CCN

CMDCAS Recognized Registrar

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Amministratore

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America

CERTIFICATE

Kendall, a Division of Tyco Healthcare Group LP
5439 State Route 49, Argyle, NY 12809 USA
(Manufacture of Sterile and Non-Sterile Medical Devices and Kits, Including: Airway Management; Urological Catheters; Dialysis Catheters; Guide Wires and Related Accessories; Vascular Catheters; and, Cardiovascular Shunts)

Kendall, a Division of Tyco Healthcare Group LP
1430 Marvin Griffin Road, Augusta, GA 30906 USA
(Manufacture of Sterile and Non-Sterile Medical Devices and Kits, Including: Wound Care)

Ludlow, a Division of Tyco Healthcare Group LP
Two Ludlow Park Drive, Chicopee, MA 01022 USA
(Manufacture of Sterile and Non-Sterile Medical Devices and Kits, Including: Hydrogel Membranes; Wound Care; Biomedical Electrodes; Medical Recording Charts; and, Operating Room Support Products.)

Kendall, a Division of Tyco Healthcare Group LP
400 Maple Street, Commerce, TX 75428 USA
(Manufacture of Sterile and Non-Sterile Medical Devices and Kits, Including: Syringes (With and Without Needles), O.R./Surgical Suction, Cardio-Thoracic Drainage; and Specimen Collection)

Kendall, a Division of Tyco Healthcare Group LP
2010 East International Speedway Boulevard, Deland, FL 32724 USA
(Manufacture of Sterile and Non-Sterile Medical Devices and Kits, Including: Needles, Lancets and Syringes (With and Without Needles); Blood Collection; and, Diagnostics)

Kendall, a Division of Tyco Healthcare Group LP
1222 Sherwood Road, Norfolk, NE 68701 USA
(Manufacture of Sterile and Non-Sterile Medical Devices and Kits, Including: Needles and Syringes (With and Without Needles); Blood Collection; and, Thermometry Related Accessories)

This Certificate is valid until: January 20, 2009

Certificate Registration No: S 951 03 1670

Issued: March 20, 2003
Revised: May 23, 2006

Gary W. Minks
Director, Certification Body

SCC Accredited CB-MS OCSM Accrédité CCN

CMDCAS Recognized Registrar

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CERTIFICATO
Amministratore

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TÜV SÜD America

CERTIFICATE

Kendall, a Division of Tyco Healthcare Group LP
130 South Main Street, Oriskany Falls, NY 13425 USA
(Manufacture of Sterile and Non-Sterile Medical Devices and Kits, Including: Filled Syringes (Water and Lubricant); Enteral Feeding and Access; GI Management; Vascular Catheters; and, Cardiovascular Shunts (Coated and Uncoated)

Kendall, a Division of Tyco Healthcare Group LP
1448 Blue Ridge Boulevard, Seneca, SC 29672 USA
(Manufacture of Sterile and Non-Sterile Medical Devices and Kits, Including: Wound Care; SCD Vascular Therapy Sleeves and Compression Stockings)

Kendall, a Division of Tyco Healthcare Group LP
98.6 Faichney Drive, Watertown, NY 13601 USA
(Manufacture of Sterile and Non-Sterile Medical Devices and Kits, Including: Enteral Feeding; Thermometry and Related Accessories; Surgical Suction; Cardio-Thoracic Drainage; Blood Bags; and SCD Vascular Therapy Pumps)

Kendall Kenmex, a Division of Tyco Healthcare Group LP
Calle 9 Sur No. 125 Ciudad Industrial, Tijuana, Mexico CP 22500
(Manufacture of Sterile and Non-Sterile Medical Devices and Kits, Including: Urological Meters; Catheters (Coated and Uncoated) and Drain Bags; Wound Care; O.R./Surgical Suction; Blood and Specimen Collection; Cardio-Thoracic Drainage; Enteral Feeding and Access; Suction and GI Management; SCD Vascular Therapy Related Accessories; Airway Management/Diagnostics; Operating Room Products; and, Irrigation Trays)

Nellcor Puritan Bennett Mexico S.A. de C.V.
37 Blvd. Insurgentes, Libriamento a la P, La Mesa, Tijuana, B.C. Mexico
(Manufacture of Urological Catheters (Coated and Uncoated); Cardio-Thoracic Drainage and Catheters; Enteral Feeding and Access; Respiratory; Airway Management/Diagnostics; Lancets; Suction and GI Management; O.R./Surgical Suction; Blood and Specimen Collection; Operating Room Support Products; Sharps Disposal; Cardio-Vascular Shunts and Catheters; Wound Care; and, Intravascular Access)

This Certificate is valid until: January 20, 2009

Certificate Registration No: S 951 03 1670

Issued: March 20, 2003
Revised: May 23, 2006

TÜV SÜD

Gary W. Minks
Director, Certification Body

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CRISTINA DENALI
Amministratore