MEDTECH
Health with Technology

MAILING ADDRESS: Near Manipur AIDS Control Society (MACS)
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E-mail: med_tch@yahoo.co.in

REGD. OFFICE: Wangkhei Khunou Chockon, Imphal East - 795 005
PHONE: +91-9862578457, E-mail: med_tch@yahoo.co.in

Mt/rims/16/03/18/2A
Dated : 18/03/2016

To
Director,
Regional Institute of Medical Sciences
Lamphel,
Imphal – 795004

Through PROF. & HOD Anesthesiology department, RIMS, Lamphel, Imphal.

Subject : Proposal for procurement of **Convatec - Fecal Incontinence Management System** on proprietary basis.

Dear Sir,

Kindly received the following enclosed necessary documents.

1. Introduction letter
2. Proprietary Certificate
3. Authorization Certificate
4. Product leaflets
5. Profoma invoice.

Thanking you

Yours truly
For MEDTECH

Kishor Thingbaijam

MEDTECH * LAMPHEL SUPER MARKET * Imphal 795004

ConvaTec

CIN: US1101KA2012PTC065530

Thursday, March 10, 2016

To,

The Medical Director,
Regional Institute of Medical Sciences,
Imphal

Sub: An Unique Patented Proprietery Offering from ConvaTec-Fecal Management Systems(FMS)

Dear Sir/Madam:

ConvaTec has been leading the way in Innovation for over 20 Years now and has been in the forefront of developing some unique products like the **Wound Dressings with Hydro fiber & Hydrocolloid Technology**, **Fecal Management Systems(FMS) called Flexi Seal**, **The AbViser™ Intra-Abdominal Pressure (IAP) Monitoring System**

Fecal Incontinience- An Concern: Epidemiology

- *C. difficile* is the major cause of antibiotic-associated diarrhea and colitis.[1] *C. difficile* can live in the gut, and under normal circumstances, causes no harm. However the risk of developing symptoms increases with the use of antibiotics.
- *C. difficile* is recognized as the most common cause of nosocomial infectious diarrhea in the nursing home setting[2] and in acute care medical wards.[3]
- Severely ill patients hospitalized in intensive care units are more likely to be treated with antibiotics.
- Skin breakdown can happen within minutes of contact with feces , Wounds can become contaminated & Increases the risk for spread of infection
- Managing incontinent patients demands considerable nursing time

How can we Prevent the Spread of Infection[1]

- The patient should be isolated while the cause of the diarrhea is determined.
- General protocols for preventing the spreading of nosocomial infections as hand washing, use of gloves, aprons, etc should be implemented and maintained until the patient has been for at least 48 hours without diarrhea.
- All clinical waste and linen from patients with *C. difficile* infection, including bedding should be considered as contaminated and should be managed in accordance with local guidelines and national guidance.[1]
- **The efficacy of Flexi-Seal® Fecal Management System to contain *C. difficile* has been proven scientifically by laboratory tests.[2]**

Containing the Spread of Infections/Fecal Incontinience through a Unique Solution- Advantages of use of FMS

- Helping to reduce the risk of skin breakdown
- Helping to reduce the risk of infection
- Helping to protect wounds from contamination
- Helping to reduce cost of managing fecal incontinence
- Helping to improve patient comfort & patient dignity
- Helping to reduce odor

- **Scientifically proven to contain Clostridium difficile**
  a. Effectively contains C.difficile.
  b. Collection bags provide an effective barrier to prevent leakage of C. difficile into the wider environment
  c. Closed system that minimizes exposure to potentially infectious waste

d. 83% of caregivers' reports on Flexi-Seal™ FMS use indicated minimal or no leakage

e. Reduces length of stay in a hospital by 3.6 days per patient

Flexi-Seal is a Dramatically Advanced Fecal Incontinence Management System, which is Patient friendly and easy to use-

- Soft, flexible retention balloon conforms to sphincter anatomy to create an effective seal that minimizes leakage and the risk of tissue necrosis
- Single finger insertion helps to ensure proper placement
- Balloon-end tubing collapses to an 8 mm diameter after deflation to minimize patient discomfort upon removal
- For patients who had baseline and follow up endoscopy, rectal mucosa was healthy after Flexi-Seal™ FMS use
- Effectively contains fecal waste and protects the patient's skin from breakdown that can lead to the development of **Pressure Ulcers**
- Flexi-Seal™ FMS helps contain potentially harmful bacteria and reduces the spread of **Nosocomial Infections**
- Prevents the spread of Infection & Protects wounds from contamination
- Reduces cost of managing fecal incontinence & Improves patient comfort & patient dignity

References:

1. Marra AR, et al. Hospital-acquired *Clostridium difficile-associated* disease in the intensive care unit setting: epidemiology, clinical course and outcome. BMC Infectious Diseases 2007, 7:42.
2. Crogan NL. *Clostridium difficile*: an emerging epidemic in nursing. Geriatr Nurs 2007; 28(3): 161-4.
3. Kyne and all .Health care costs and mortality associated with nosocomial diarrhea due to *Clostridium difficile* .CID 2002:34 346.353
4. Department of Health, Health Protection Agency, Best Practice Guidance, *Clostridium difficile* infection: how to deal with the problem, p 16 and 21, Dec 2008
5. Containment of *C. difficile* by the Flexi-Seal® Fecal Management System, an In Vitro study Data presented at the ConvaTec sponsored Symposium "Challenges of Fecal Incontinence", WUWHS, Toronto, June 7th 2008.
6. Jarvis WR, Scholsser JA, Jarvis AA, Chinn RY. National point prevalence study for Clostridium difficile in the US health care facility inpatients, 2008. The Association for Professionals in Infection Control and Epidemiology, Inc (APIC). Am J Infect Control 2009;37:263-70.
7. Kramer A, et al: How long do nosocomial pathogens persist on inanimate surfaces?A systematic review. *BMC Infectious Diseases* 2006, 6:130
8. Guide to the elimination of Clostridium difficile in Healthcare settings.", Association for Professionals in Infection Control and Epidemiology (APIC) 2008.
9. Containment of Clostridium difficile by the Flexi-Seal® Fecal Management System: an In Vitro Study. WHRI3107 MA106. May 8 2008. Data on file, ConvaTec.
10. Use of Filtered Fecal Collection Bags to Contain Clostridium difficile: an In-vitro Study. WHR13274 MA138. 25 September 2009. Data on file, ConvaTec
11. Why Flexi-Seal® FMS can help with C. difficile control. A series of customer experiences, Maidstone and Tunbridge Wells NHS Trust, 2008, ConvaTec Inc.
12. Containment of *Clostridium difficile* by the Flexi-Seal® Fecal Management System: an In Vitro Study. WHRI3107 MA106. May 8 2008. Data on file, ConvaTec
13. Use of Filtered Fecal Collection Bags to Contain *Clostridium difficile*: an In vitro Study. WHR13274 MA138. 25 September 2009. Data on file, ConvaTec.
14. Containment of Clostridium difficile by the Flexi-Seal® Fecal Management System: an In Vitro Study. WHRI3107 MA106. May 8 2008. Data on file, ConvaTec.

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CIN: US1101KA2012PTC065530

15. Use of Filtered Fecal Collection Bags to Contain Clostridium difficile: an in vitro Study WHR13274 MA138. 25 September 2009. Data on file, ConvaTec. 3. Flexi-Seal® SIGNAL® FMS Directions for Use, ConvaTec.

16. [1]Zhan C, Miller M. *The Journal of American Medical Association*. 2003 Oct; 290: 1868-1874

Clinically Fecal Management Systems(FMS) have demonstrated and sctificaaly established on containing the Spread of Nosocomial Infections as compared to the conventional use of Diapers. I am sure you will provide us an opportunity to Interact, Demonstrate and make us your choice of partner in transforming Patient Care. In case you wish to stay in touch with us to know more, Please feel free to write to me at the address as below or speak to our **Area Sales Manager Mr. Jyoti Prasad Kakati who can be contacted on +91 9707167188** and our team shall be more than pleased to offer solutions to transform patient care by enabling technology for you.

We encourage you and welcome you to visit our website at www.convatec.co.in to know more about our exciting ranges that we have to offer or call us for a demo.

Assuring of our best attention and services at all times.

Yours Sincerely,

A. Ray

Arnab Ray
Regiona Sales Head-Eastern Region
Hand Phone: +91 9836344569

ConvaTec

CIN: US1101KA2012PTC065530

Thursday, March 10, 2016

Manufacturer's Authorization Form

To,

The Medical Director,
Regional Institute of Medical Sciences,
Imphal

Sub: Authorization Letter for Supply of our Wound Products.

Dear Sir,

We **ConvaTec India Private Limited** who are established and reputable manufacturers of Wound , Ostomy and Critical Care and Continence Product and having its India registered office at **S-604, World Trade Centre, Beside Brigade Gateway, Malleswaram- Yeshwanthapur, Dr.Rajkumar Road, Malleswaram, Bangalore-560055** here Authorise ***M/S Healthcare Associates, 13, Elgin Road Kolkata-700 020*** has been appointed as our Distributor for ConvaTec Advance Wound Range of Products manufactured & marketed by ConvaTec for the Eastern Region.

In this regard M/S. M/S Healthcare Associates as an authorized distributor is in turn authorized to appoint their dealer ***M/s MedTech Lamphel Super Market, Near HDFC ATM Booth, Imphal*** as their representative for the Wound Range of Products, to quote, negotiate and supply the products and collect payments on our behalf. This authorization will be valid until the last day of the contractual terms, i.e. 7th March 2017.

We hereby declare that we have not been blacklisted by any of the nodal Central/State Government /Hospital Agencies.

Yours Sincerely,

ConvaTec India Pvt. Ltd. Bangalore

Deepak Kumar
General Manager
ConvaTec India Private Limited
DID: 080-49151001/49151010

ConvaTec Global Development Centre, First Avenue, Deeside Industrial Park, Deeside, Flintshire CH5 2NU
Tel: +44 (0) 1244 584333. Fax: +44 (0) 1244 584311
www.convatec.com

PROPRIETARY CERTIFICATE

Flexi-Seal® FMS

Flexi-Seal® Fecal Management System

This is to certify that Flexi-Seal® FMS is a proprietary product of ConvaTec. U.S. Patent Nos. 8,016,816 & 8,827,970 and European Patent No. EP1514572.

Flexi-Seal® FMS is a soft silicone catheter that is inserted into the rectum for fecal management to contain and divert fecal waste in order to protect the patient's skin and keep the bedding clean. There is a low pressure retention balloon at one end and a connector for attaching the collection bag at the other end.

Flexi-Seal® FMS is indicated for the fecal management of patients with little or no bowel control and liquid or semi-liquid stool.

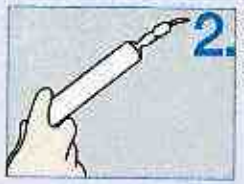
29/Sep/2015.

Steve Bishop
Vice President Research and Development

Directions for using Flexi-Seal® FMS

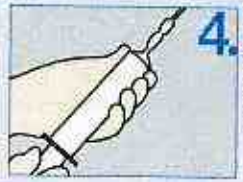
In addition to the system, gloves and lubricant will be required.

1. Use the cuff-finger pocket to guide insertion of the retention balloon.



2. Using the provided syringe, connect to the inflation tube and fill the retention balloon with water or saline.

3. Securely snap the collection bag to the connector at the end of the catheter. Replace the collection bag as necessary. Snap the cap onto the used bag and discard in accordance with institutional protocol.



4. To remove the catheter, connect the syringe to the inflation port. Then deflate the retention balloon by withdrawing the water or saline with the syringe.

This product cannot be left in place for more than 29 days.

Ordering information

Catalog #	Description	Quantity
411100	Flexi-Seal FMS	Includes 3 collection bags
411101	Replacement collection bags	10

Examples of products that may be used with Flexi-Seal FMS

Aloe Vesta® Cleansing Foam
A no-rinse, pH-balanced cleanser designed for all-over body use, including hair and perineum.

Aloe Vesta® Protective Ointment
An ointment designed to act as a barrier for routine use in incontinence care by moisturizing and protecting the skin. It seals out wetness and provides a barrier against urine and feces.

Sensi-Care® Protective Barrier
A zinc oxide–based barrier that provides extra protection for high-risk skin or weepy and denuded skin.

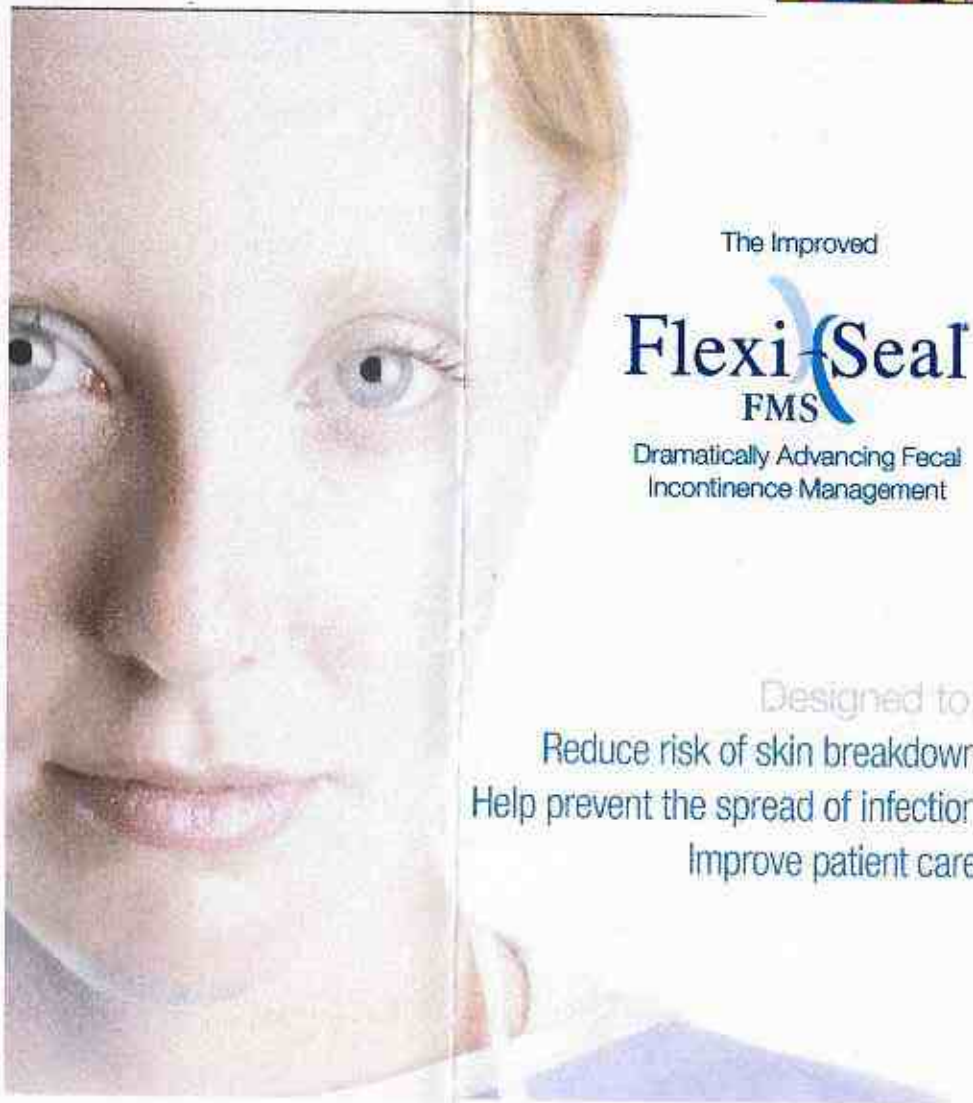
Aloe Vesta® Antifungal Ointment
A petrolatum-based ointment that forms an occlusive barrier to repel moisture and soften affected skin, while it relieves itching, scaling, cracking, and discomfort.

Please see package insert for complete instructions for Use.

To learn more, call
1-800-422-8811
M-Th, 8:30 AM–5:00 PM, EST
Fri, 8:30 AM–6:00 PM, EST
Sat, 10:00 AM–2:00 PM, EST
www.convatec.com

Our world is what we make of it™

ConvaTec



The Improved

Flexi-Seal FMS

Dramatically Advancing Fecal Incontinence Management

Designed to:
Reduce risk of skin breakdown
Help prevent the spread of infection
Improve patient care

ConvaTec

The IMPROVED Flexi-Seal® FMS is now easier to use with 4 new features!

Flexi-Seal® FMS innovations can save nursing time and improve patient comfort.

- Closed-end collection bag helps prevent spread of infection.
- The soft, low-pressure balloon is designed to minimize the chance of tissue necrosis.
- The soft, flexible silicone catheter can collapse to an 8 mm diameter after insertion and conforms to sphincter tone and anatomy.
- Flexi-Seal® FMS is entirely latex free.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2004

Ms. Nancy Regulski
Manager, Regulatory Affairs
ConvaTec, A Division of E.R. Squibb and Sons, L.L.C.
200 Headquarters Park Drive
SKILLMAN NJ 08558

Re: K032734
Trade/Device Name: ConvaTec Fecal Management System
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: January 21, 2004
Received: January 22, 2004

Dear Ms. Regulski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ConvaTec GDC
First Avenue
Deeside Industrial Park
Deeside
Flintshire CH5 2NU
United Kingdom
Telephone: 01244 584300

DECLARATION OF CONFORMITY

Flexi-Seal® Faecal Management Kit
(TP12-007 & TP11-053)

Classification (MDD Annex IX): Class IIa, Rule 5

This is to confirm that the medical device products listed below comply with the Essential Requirements laid down in Annex I of Council Directive 93/42/EEC and are CE-marked in accordance with the requirements of Annex II of this Directive.

Product Reference: 411100

Manufacturer: ConvaTec Limited

Address: First Avenue
Deeside Industrial Park
Deeside
Flintshire CH5 2NU
United Kingdom

Notified Body: The British Standards Institute (0086)

The validity of this Declaration of Conformity corresponds with the expiration date of Full Quality Assurance Certificate (CE 00364).

Issued in: Deeside, UK

Signed: Date:

Linda Harris
Director of Regulatory Affairs
Pre-market

19/12/2014
(dd/mm/yyyy)

Flexi-Seal® Faecal Management Kit
(TP12-007 & TP11-053)

HISTORY PAGE

Version No.	Checked by	Date	Comment
1		12/10/04	First Issue
2		01/08/08	New letter headed paper
3		16/03/09	Addition of Fortune Medical as an alternative supplier
4	LH	19/12/14	Updated following change to collection bag film; ref. CCR-HAI-2014-0005. Revised to include reference to place of issue and CE Certificate number, as per the requirements of BS EN ISO/IEC 17050-1: 2010.

bsi.

Certificate

Production Quality Assurance

No. CE 56172

Issued to:

ConvaTec Limited
First Avenue
Deeside Industrial Park
Deeside
Flintshire
CH5 2NU
United Kingdom

In respect of:

Those aspects of Annex V related to securing and maintaining sterility in the manufacture of wound management dressings, ostomy products and accessories, incontinence appliances, applicator nozzles; securement devices; catheters, cannulae and accessories (excluding intravascular, epidural and spinal); urinary collection systems and accessories; suction sets; tubing; bags and accessories; airways management accessories; clamp and cutter for umbilical cord.

The manufacture of sterile intra-abdominal pressure monitoring devices.

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **22 Dec 2000** Date: **20 Sep 2013**

Expiration Date: **20 Oct 2018**

Conditions of Approval
Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.
This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate unless specifically agreed with BSI.

...making excellence a habit.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 (0)845 080 9000

MEDTECH
Health with Technology

MAILING ADDRESS: Near Manipur AIDS Control Society (MACS)
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REGD. OFFICE: Wangkhei Khunou Checkon, Imphal East - 795 005
PHONE: +91-9862578457, E-mail: med_tch@yahoo.co.in

Mt/rims/16/03/18/2A
Dated : 18/03/2016

To
Director,
Regional Institute of Medical Sciences
Lamphel,
Imphal – 795004

Subject : PROFOMA INVOICE for Fecal Incontinence Management System

Sl no.	Product code	Particulars	Qty	Rate	Amount
01.	411100	FLEXI-SEAL FMS KIT (1X1PK) US (Fical Management system)	1 no.	10,396.00	10,396.00
RUPEES TEN THOUSAND THREE HUNDRED AND NINTY SIX ONLY					
02.	411101	FLEXI-SEAL FMS COLLECTION BAGS (1X10PK) US (Replacement collection bags)	1 set (10 pcs)	2,978.00	2,978.00
RUPEES TWO THOUSAND NINE HUNDRED SEVENTY EIGHT ONLY					

Terms and conditions:

1. Price quoted is exclusive of VAT.
2. FOR Destination.
3. Delivery within 1 - 2 WEEKS.

Thanking you and assuring our best service,

Yours truly,
For Medtech

Kishor Thingbaijam

MEDTECH * LAMPHEL SUPER MARKET * Imphal 795004