



Medicines & Healthcare products  
Regulatory Agency

151 Buckingham Palace Road  
London SW1W 9SZ  
United Kingdom

[mhra.gov.uk](http://mhra.gov.uk)

SAE 188/V10916/1

20/11/2017 09:37:32

## Medicines and Healthcare Products Regulatory Agency

On behalf of the Department of Health

### CERTIFICATE OF FREE SALE FOR EXPORTATION OF MEDICAL PRODUCTS TO VIETNAM

It is hereby certified that, on the basis of information provided, the products named below and detailed in the attached schedule (if applicable), which are manufactured by; **ConvaTec Limited**, have been affixed with the CE mark under the Medical Devices Directive 93/42/EEC as transposed into UK legislation (UK Medical Devices Regulations 2002 SI No. 618, as amended), and therefore may be freely sold in all member states of the European Economic Area including the United Kingdom.

#### See attached schedule

Where appropriate, Certificates of Free Sale are issued as a service to UK exporters. A Certificate of Free Sale should not be taken as a Government endorsement of any product that is referred to on the certificate.

Yours sincerely,

**Funmi Taiwo**

Certificate of Free Sale Administration Team  
Signed on Behalf of MHRA



**APOSTILLE**

(Convention de La Haye du 5 octobre 1961)

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**This public document**  
Le présent acte public / El presente documento público

**2. Has been signed by**  
a été signé par Funmi Taiwo  
ha sido firmado por

**3. Acting in the capacity of**  
agissant en qualité de Official of the Medicines and Healthcare products  
quien actúa en calidad de Regulatory Agency (MHRA)

**4. Bears the seal / stamp of**  
est revêtu du sceau / timbre de Not applicable  
y está revestido del sello / timbre de

**Certified**  
Attesté / Certificado

**5. at** London **6. the** 30 November 2017  
à / en le / el día

**7. by** Her Majesty's Principal Secretary of State  
par / por for Foreign and Commonwealth Affairs

**8. Number** APO-639899  
sous no / bajo el numero

**9. Seal / stamp**  
Sceau / timbre  
Sello / timbre



**10. Signature** B. Redman  
Signature  
Firma

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by  
u. Anh  
20. Anh

12. 2017  
u. Anh  
Ailen  
f



CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ  
CONSULAR AUTHENTICATION

1. Quốc gia / Country: Việt Nam

Giấy tờ, tài liệu này  
This public document

2. do Ông (Bà) B. Redman ký  
has been signed by

3. với chức danh Cán bộ Lãnh Sự  
acting in the capacity of

4. và con dấu của B. Ngoại giao Anh  
bears the seal/stamp of

được chứng nhận / hợp pháp hóa lãnh sự  
Certified

5. tại London 6. ngày 05/12/2017  
at the

7. Cơ quan cấp Đ.S. Việt Nam tại Anh  
by

8. Số 5125 và Ai len  
No

Ký tên và đóng dấu  
Signature and seal/stamp

Bai 'thư' thư' nhất



Nguyễn Diệu Hà

Schedule of Devices requested for  
 Ordered on  
 Directive/Class  
 Mfr Name

ord-20171120-093444-mqxx  
 20/11/2017  
 93/42/EEC  
 ConvaTec Limited

No	Device Make	Device Model	Classification	Manufacturing Site
1	LITTLE ONES ONE PIECE UROSTOMY POUCH (1X15PK)	020917	I Rule 1	ConvaTec Dominican Republic, Inc. Carretera Sanchez, Km. 18.5 Parque Industrial Itabo, S.A. Haina, San Cristobal, 91000 Dominican Republic
2	ESTEEM SYNERGY DRAINABLE POUCH 48MM(1X10PK)	416798	I Rule 1	
3	ESTEEM SYNERGY STOMAHESIVE SKIN BARRIER WITH FLEXIBLE COLLAR	405457	I Rule 1	
4	SUR-FIT NATURA UROSTOMY POUCH 38MM (1X10)	401534	I Rule 1	
5	SUR-FIT NATURA UROSTOMY POUCH 45MM (1X10PK)	401535	I Rule 1	
6	STOMAHESIVE SEAL 48MM (1X10PK)	413503	I Rule 1	
7	STOMAHESIVE SEAL THIN 48MM (1X10PK)	413504	I Rule 1	
8	STOMAHESIVE SEAL 98MM (1X10)	413505	I Rule 1	
Legal Manufacturer: ConvaTec Limited, First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, United Kingdom				

**End of schedule. No additional products past this point.**

