

	Effective Date:	As per signature		
	Status:	Effective	Version:	3.0, CURRENT
	Group:	Change Control	Sites:	CC-Deeside-R&D
	Artifact Name:	Form	Name:	FORM-014357
	Title:	WI-0506 Declaration of Conformity Form		

EU Declaration of Conformity

EuroTec Closed Pouches

Technical Documentation ; MDR OSTTF 024 – EuroTec Closed Pouches

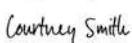
Issued by: ConvaTec

We hereby declare;

- that the listed product/s comply with the applicable general safety and performance requirements and provisions of EU Medical Device Regulation (EU) 2017/745 and any other applicable European Union legislation
- that this EU declaration of conformity is issued under the sole responsibility of ConvaTec.

Legal Manufacturer:	ConvaTec Limited, First Avenue, Deeside Industrial Park, Deeside, Flintshire CH5 2NU, United Kingdom
Singel Reg # (SRN):	GB-MF-000001770
Authorized Representative:	Unomedical a/s, Aaholmvej 1-3, Osted, 4320, Lejre, Denmark
Product Name:	EuroTec Closed Pouches
Basic UDI:	768455OST0049FR
Intended Use:	For the management of stomal output.
GMDN Code & Name:	31066 - One-piece intestinal ostomy bag, closed ended 31067 - Multiple-piece intestinal ostomy bag, closed-ended
Device(s) & Cat. #:	Reference to Appendix A
Risk Class:	Class I (MDR Annex VIII)
Conformity Assessment Route:	Annex II and III of EU Medical Device Regulation (EU) 2017/745
Notified Body:	Self Certified
Certificate(s):	N/A

Legal Manufacturer authorized signature:

Signed by:


 Signer Name: Courtney Smith
 Signing Reason: I approve this document
 Signing Time: Apr 10, 2025 | 2:19:35 PM BST
 18C584297FF34C80A5D3283D05D64343

Signature: _____ **Date:** Apr 10, 2025

Courtney Smith

Senior Director, Regulatory Affairs Ostomy Care

Place of Issue: Boston, Massachusetts

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Appendix A: Products

ICC Codes	SAP Codes	Product Description	GMDN
421973	1747289	CLM CLD L WIN 13-60MM (1X30PK)EUR	31066
422640	1747427	CLM CLD L WIN 22MM (1X30PK)EUR	31066
422641	1747428	CLM CLD L WIN 25MM (1X30PK)EUR	31066
422642	1747429	CLM CLD L WIN 28MM (1X30PK)EUR	31066
421974	1747290	CLM CLD L WIN 32MM (1X30PK)EUR	31066
422644	1747430	CLM CLD L WIN 35MM (1X30PK)EUR	31066
422645	1747451	CLM CLD L WIN 38MM (1X30PK)EUR	31066
421975	1747291	CLM CLD L WIN 45MM (1X30PK)EUR	31066
421948	1747274	CLM CLD M BG 13-50MM (1X30PK)EUR	31066
421949	1747275	CLM CLD M BG 25MM (1X30PK)EUR	31066
421950	1747276	CLM CLD M BG 28MM (1X30PK)EUR	31066
421951	1747277	CLM CLD M BG 32MM (1X30PK)EUR	31066
421976	1747292	CLM CLD M BG 35MM (1X30PK)EUR	31066
421981	1747293	CLM CLD ML WIN 13-60MM (1X30PK)EUR	31066
422656	1747431	CLM CLD ML WIN 22MM (1X30PK)EUR	31066
422657	1747432	CLM CLD ML WIN 25MM (1X30PK)EUR	31066
422658	1747433	CLM CLD ML WIN 28MM (1X30PK)EUR	31066
422659	1747434	CLM CLD ML WIN 32MM (1X30PK)EUR	31066
422660	1747435	CLM CLD ML WIN 35MM (1X30PK)EUR	31066
422661	1747436	CLM CLD ML WIN 38MM (1X30PK)EUR	31066
422662	1747437	CLM CLD ML WIN 45MM (1X30PK)EUR	31066
421952	1747278	CLM CLD XL OVAL WIN 70X110MM (1X30PK)EUR	31066
421956	1747281	CLM SCVX CLD L WIN 13-35MM (1X10PK)EUR	31066
421957	1747282	CLM SCVX CLD L WIN 13-44MM (1X10PK)EUR	31066
422406	1747412	CLM SCVX CLD L WIN 22MM (1X10PK)EUR	31066
421958	1747283	CLM SCVX CLD L WIN 25MM (1X10PK)EUR	31066
421959	1747560	CLM SCVX CLD L WIN 28MM (1X10PK)EUR	31066
421960	1747284	CLM SCVX CLD L WIN 32MM (1X10PK)EUR	31066
421961	1747285	CLM SCVX CLD L WIN 35MM (1X10PK)EUR	31066
422407	1747413	CLM SCVX CLD L WIN 38MM (1X10PK)EUR	31066
421962	1747286	CLM SCVX CLD L WIN 41MM (1X10PK)EUR	31066
421954	1747279	CLM SCVX OVAL CLD L 44X29MM (1X10PK)EUR	31066

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421955	1747280	CLM SCVX OVAL CLD XL 54X37MM (1X10PK)EUR	31066
421942	1747267	CLM SCVX CLD ML WIN 13-35MM (1X10PK)EUR	31066
421943	1747268	CLM SCVX CLD ML WIN 13-44MM (1X10PK)EUR	31066
421940	1747265	CLM SCVX CLD ML WIN 22MM (1X10PK)EUR	31066
421944	1747269	CLM SCVX CLD ML WIN 25MM (1X10PK)EUR	31066
421945	1747270	CLM SCVX CLD ML WIN 28MM (1X10PK)EUR	31066
421946	1747271	CLM SCVX CLD ML WIN 32MM (1X10PK)EUR	31066
421947	1747273	CLM SCVX CLD ML WIN 35MM (1X10PK)EUR	31066
422688	1747457	CLM SCVX CLD ML WIN 38MM (1X10PK)EUR	31066
422689	1747458	CLM SCVX CLD ML WIN 41MM (1X10PK)EUR	31066
421963	1747287	CLM SCVX CLD XL WIN 13-54MM (1X10PK)EUR	31066
422735	1747426	OSM CLD FLAT L WIN 13-65MM (1X30PK)EUR	31066
421990	1747297	COM PCH CLD L BG 38MM (1X30PK)EUR	31067
421991	1747298	COM PCH CLD L BG 45MM (1X30PK)EUR	31067
423924	1747556	COM PCH CLD L BG NO FIL 45MM (1X30PK)EUR	31067
421992	1747299	COM PCH CLD L BG 57MM (1X30PK)EUR	31067
423925	1747557	COM PCH CLD L BG NO FIL 57MM (1X30PK)EUR	31067
421989	1747296	COM PCH CLD L BG 70MM (1X30PK)EUR	31067
421995	1747300	COM PCH CLD M BG 45 MM (1X30PK)EUR	31067
421996	1747301	COM PCH CLD M BG 57 MM (1X30PK)EUR	31067
421998	1747302	COM PCH CLD ML BG 45 MM (1X30PK)EUR	31067
421999	1747303	COM PCH CLD ML BG 57 MM (1X30PK)EUR	31067
422803	1747492	COM PCH CLD ML BG 70 MM (1X30PK)EUR	31067
422807	1747494	COM PCH CLD XL WIN 100MM (1X15PK)EUR	31067
422806	1747493	COM PCH CLD XL WIN 85MM (1X15PK)EUR	31067
421941	1747266	CLM CAP BG 13-50MM (1X30PK)EUR	31066