

	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
GMDN Code & Name:	31066 – One-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:**


DocuSigned by:

 Signer Name: Courtney Smith
 Signing Reason: I approve this document
 Signing Time: Jun 26, 2024 | 2:49:10 PM BST
 18C584297FF34C80A5D3283D05D64343 **Date:** Jun 26, 2024

Signature: _____
 Courtney Smith
 Senior Director, Regulatory Affairs Ostomy Care
 Place of Issue: Boston, Massachusetts

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Appendix A: Products

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

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1747280	421955	CLM SCVX OVAL CLD XL 54X37MM (1X10PK)EUR
1747267	421942	CLM SCVX CLD ML WIN 13-35MM (1X10PK)EUR
1747268	421943	CLM SCVX CLD ML WIN 13-44MM (1X10PK)EUR
1747265	421940	CLM SCVX CLD ML WIN 22MM (1X10PK)EUR
1747269	421944	CLM SCVX CLD ML WIN 25MM (1X10PK)EUR
1747270	421945	CLM SCVX CLD ML WIN 28MM (1X10PK)EUR
1747271	421946	CLM SCVX CLD ML WIN 32MM (1X10PK)EUR
1747273	421947	CLM SCVX CLD ML WIN 35MM (1X10PK)EUR
1747457	422688	CLM SCVX CLD ML WIN 38MM (1X10PK)EUR
1747458	422689	CLM SCVX CLD ML WIN 41MM (1X10PK)EUR
1747287	421963	CLM SCVX CLD XL WIN 13-54MM (1X10PK)EUR
1747426	422735	OSM CLD FLAT L WIN 13-65MM (1X30PK)EUR