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EC Declaration of Conformity

Manufacturer Name: EuroTec B.V.
 Address: Schotsbossenstraat 8, 4705 AG Roosendaal, The Netherlands

EuroTec B.V. / The Manufacturer herewith declares that the products mentioned in this DoC conform to the applicable general safety and performance requirements and provisions of the European Medical Devices Regulations ((EU) 2017/745).

Generic name	Ostomy pouches	
Trade/ Brand Name(s):	Combimate	
Product Codes	Applicable product codes are listed in attachment A.	
Intended use	Ostomy Pouches are intended to be used in conjunction with compatible body side wafers for collection of stomal output for ostomates.	
Classification and Rule (Include Sterility / Measuring if applicable)	Following Chapter 3, paragraph 4.1 of Annex VIII of the Medical Device Regulations ((EU) 2017/745), the ostomy pouches are classified as a Class I device. The ostomy pouches are non-measuring and non-sterile.	
Route of conformity assessment	Annex IX of Medical Device Regulations ((EU) 2017/745).	
Single Registration Number	NL-MF-000002060	
Basic UDI-DI	8717905ETOST0002TE	
Harmonized Standards Applied:	EN ISO 9001:2015	EN ISO 10993-1:2009
	EN ISO 13485:2016	EN 1041:2008+A1:2013
	EN ISO 10993-10:2013	EN ISO 3166-1:2014
	EN ISO 10993-5:2009	EN ISO 639-1:2002
	EN ISO 10993-12:2012	EN ISO 14971:2019
	EN ISO 15223-1:2016	

This declaration of conformity is issued under the sole responsibility of the manufacturer.
 Issued in Roosendaal, The Netherlands. Signed for and on behalf of EuroTec B.V.

Name: Gary Barrett
 Vice President Regulatory affairs
 ConvaTec Inc.

Date: June 9 2021

Attachment A

Trade name	Product code	UDI
COMBIMATE	CCB 245	08717228160066
COMBIMATE	CCB 257	08717228160073
COMBIMATE	CLB 238	08717228160165
COMBIMATE	CLB 257	08717228160189
COMBIMATE	CLB 270	08717228160196
COMBIMATE	CMB 238	08717228160455
COMBIMATE	CMB 245	08717228160462
COMBIMATE	CMB 257	08717228160479
COMBIMATE	CMLB 238	08717228164095
COMBIMATE	CMLB 245	08717228164088
COMBIMATE	CMLB 257	08717228163760
COMBIMATE	CMLB 270	08717228164347
COMBIMATE	CSB 245	08717228160639
COMBIMATE	CXLT 2100	08717228160752
COMBIMATE	CXLT 285	08717228160769
COMBIMATE	ILBV 238	08717905177066
COMBIMATE	ILBV 245	08717905177073
COMBIMATE	ILBV 245Z	08717905185207
COMBIMATE	ILBV 257	08717905177080
COMBIMATE	ILBV 257Z	08717905185214
COMBIMATE	ILBV 270	08717905177097
COMBIMATE	ILT 245B	08717905198887
COMBIMATE	ILT 257B	08717905195862
COMBIMATE	ILT 270B	08717905195879
COMBIMATE	IMBV 238	08717905177301
COMBIMATE	IMBV 245	08717905177318
COMBIMATE	IMBV 257	08717905177349
COMBIMATE	ISBV 245	08717905177455
COMBIMATE	ISBV 257	08717905177462
COMBIMATE	IXLT 2100B	08717905195893
COMBIMATE	IXLT 285B	08717905195886
COMBIMATE	IXLTV 2100	08717905195855
COMBIMATE	IXLTV 285	08717905195848
COMBIMATE	ULT 238B	08717228162367
COMBIMATE	ULT 245B	08717228162381
COMBIMATE	ULT 257B	08717228162404
COMBIMATE	ULT 270B	08717228162428
COMBIMATE	UMT 238B	08717905174256
COMBIMATE	UMT 245B	08717905174263
COMBIMATE	UMT 257B	08717905174270
COMBIMATE	UXST 238B	08717228163647
COMBIMATE	UXST 245B	08717228162497

EC Declaration of Conformity document history

Ostomy pouches Combimate

Issue number	Date	Comment
1	22 March 2021	First issue
2	26 May 2021	Added Basic UDI check digits. Adjusted route of conformity assessment.