



Declaration of CE Conformity

Product Identification			
Product Name	REF	EDMS Code	Registration Date and Number
CerTest FOB	F820001F F820001FC F740001F F740001FC	12.03.90.04.00	30/08/2004 ES/CA01/02/269823
CerTest FOB 50+200	FB882001F FB882001FC	12.70.03.90.00	15/04/2011 RPS/287/2011
CerTest FOB-Transferrin	FT882001F FT882001FC FR740301F FR740301FC	12.70.03.90.00&12.7 0.01.90.00	12/12/2008 ES/CA01/02/4240905
CerTest Transferrin	TF820001F TF820001FC	12.70.01.90.00	19/12/2013 RPS/967/2013
CerTest Calprotectin	CP820001F CP820001FC CP740001F CP740001FC	12.70.01.90.00	07/09/2010 ES/CA01/02/326990-2
CerTest Calprotectin 50+200	CC882001F CC882001FC	12.70.01.90.00	24/02/2011 RPS/284/2011
CerTest Lactoferrin	LT820001F LT820001FC LT740001F LT740001FC	12.70.01.90.00	12/12/2008 ES/CA01/02/4240906
CerTest Calprotectin-Lactoferrin	CL882001F CL882001FC CR740301F CR740301FC	12.70.01.90.00	07/09/2011 ES/CA01/02/326990-3
CerTest FOB+Transferrin+Calprotectin+ Lactoferrin	FC862001F FC862001FC	15.70.03.90.00 & 12.70.01.90.00	15/04/2011 RPS/287/2011
CerTest Rotavirus	R820001V R820001VC R740001V R740001VC	15.04.80.06.00	17/02/2004 ES/CA01/02/49023-2
CerTest Adenovirus	AD820001V AD820001VC AD740001V AD740001VC	15.04.80.01.00	17/02/2004 ES/CA01/02/49023-3
CerTest Rotavirus-Adenovirus	XR882001V XR882001VC XR740301V XR740301VC	15.04.80.06.00 & 01.00	17/02/2004 ES/CA01/02/49023-4
CerTest Astrovirus	AT820001V AT820001VC AT740001V AT740001VC	15.70.90.90.00	02/02/2007 ES/CA01/02/38059-1
CerTest Rotavirus+Adenovirus+Astrovirus	RT872001V RT872001VC	15.04.80.06.00, 15.04.80.01.00 & 15.70.90.90.00	24/02/2011 Registration number has been requested from Spanish Agency of Medical Products and Medical Devices (AEMPS)
CerTest Norovirus	NN820001V NN820001VC NN740001V NN740001VC	15.70.90.90.00	02/02/2007 ES/CA01/02/38059-2
CerTest Norovirus GI+GII	NV882001V NV882001VC NV740301V NV740301VC	15.70.90.90.00	24/09/2013 RPS/872/2013
CerTest Rotavirus +Norovirus GI/GII	RN882001V RN882001VC	15.70.90.90.00	24/09/2013 RPS/872/2013



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CerTest ROTA+ADENO+NORO	RA872001V RA872001VC	15.70.90.90.00	07/02/2014 RPS/30/2014
CerTest Rota+Adeno+Astro+Noro	RG862001V RG862001VC	15.70.90.90.00	24/09/2013 RPS/872/2013
CerTest Enterovirus	EV820001V EV820001VC EV740001V EV740001VC	15.70.90.90.00	29/03/2010 Registration number has been requested from Spanish Agency of Medical Products and Medical Devices (AEMPS)
CerTest Enterovirus 71	EN820001V EN820001VC	15.70.90.90.00	15/07/2016 RPS/404/2016
CerTest HAV	HA820001V HA820001VC HA740001V HA740001VC	12.70.02.90.00	12/12/2008 ES/CA01/02/4240902
CerTest H. pylori	P820001V P820001VC P740001V P740001VC	15.70.01.02.00	17/11/2005 ES/CA01/02/370037-13
CerTest H. pylori+Transferrin	PT882001VF PT882001VFC	15.70.01.02.00 & 12.70.01.90.00	24/02/2011 Registration number has been requested from Spanish Agency of Medical Products and Medical Devices (AEMPS)
CerTest Clostridium difficile antigen GDH	GD820001V GD820001VC GD740001V GD740001VC	15.70.01.06.00	07/02/2012 RPS/114/2012
CerTest GDH+Lactoferrin	GF882001VF GF882001VFC	15.70.01.06.00&12.7 0.01.90.00	24/05/2013 RPS/635/2013
CerTest Clostridium difficile Toxin A+B	CD882001V CD882001VC CD740301V CD740301VC	15.70.01.06.00	07/02/2012 RPS/114/2012
CerTest C. difficile GDH+Toxin A+B	GX872001V GX872001VC	15.70.01.06.00	20/09/2013 RPS/869/2013
CerTest C. difficile GDH+Toxin A+B+Lactoferrin	LX8620001VF LX8620001VFC	15.70.01.06.00 &12.70.01.90.00	20/09/2013 RPS/869/2013
CerTest E. coli O157:H7	E820001V E820001VC E740001V E740001VC	15.01.15.01.00	17/11/2005 ES/CA01/02/370037-16
CerTest EHEC VT1+VT2	SX882001V SX882001VC SX740301V SX740301VC	15.01.15.02.00	18/09/2013 RPS/866/2013
CerTest E. coli O157+VT1+VT2	EX872001V EX872001VC	15.70.01.90.00	26/09/2013 RPS/879/2013
CerTest Campylobacter	CA820001V CA820001VC CA740001V CA740001VC	15.70.01.90.00	24/11/2009 ES/CA01/02/464691-1
CerTest Salmonella	SA820001V SA820001VC SA740001V SA740001VC	15.70.01.90.00	24/11/2009 ES/CA01/02/464691-2
CerTest Salmonella typhi	ST820001V ST820001VC ST740001V ST740001VC	15.70.01.90.00	07/09/2010 ES/CA01/02/326990-1
CerTest Salmonella paratyphi	SP820001V SP820001VC	15.70.01.90.00	20/03/2012 RPS/227/2012
CerTest Salmonella typhi+paratyphi	TP882001V TP882001VC	15.70.01.90.00	20/03/2012 RPS/227/2012



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Product Name	REF	EDMS Code	Registration Date and Number
CerTest <i>Listeria</i>	LM820001V LM820001VC LM740001V LM740001VC	15.70.01.90.00	24/11/2009 ES/CA01/02/464691-3
CerTest <i>Shigella</i>	SH820001V SH820001VC SH740001V SH740001VC	15.70.01.90.00	25/11/2010 ES/CA01/02/422681-1
CerTest <i>Shigella dysenteriae</i>	SD820001V SD820001VC SD740001V SD740001VC	15.70.01.90.00	25/11/2010 ES/CA01/02/422681-2
CerTest <i>Shigella dysenteriae</i> +STX	DX882001V DX882001VC	15.70.01.90.00	10/01/2014 RPS/9/2014
CerTest <i>Yersinia enterocolitica</i> O:3	YE820001V YE820001VC YE740001V YE740001VC	15.70.01.90.00	24/05/2013 RPS/635/2013
CerTest <i>Yersinia enterocolitica</i> O:9	YC820001V YC820001VC YC740001V YC740001VC	15.70.01.90.00	21/03/2014 RPS/87/2014
CerTest <i>Yersinia enterocolitica</i> O:3 + O:9	YS882001V YS882001VC	15.70.01.90.00	24/05/2013 RPS/635/2013
CerTest <i>Crypto</i>	K820001V K820001VC K740001V K740001VC	15.05.10.07.00	04/06/2004 ES/CA01/02/179864-2
CerTest <i>Giardia</i>	G820001V G820001VC G740001V G740001VC	15.05.10.08.00	17/11/2005 ES/CA01/02/370037-14
CerTest <i>Crypto</i> + <i>Giardia</i>	N882001V N882001VC NR740301V NR740301VC	15.05.10.07.00 & 08.00	17/11/2005 ES/CA01/02/370037-15
CerTest <i>Entamoeba</i>	EH820001V EH820001VC EH740001V EH740001VC	15.70.05.90.00	18/09/2013 RPS/866/2013
CerTest <i>Crypto</i> + <i>Giardia</i> + <i>Entamoeba</i>	NH872001V NH872001VC	15.70.05.90.00	24/09/2013 RPS/872/2013
CerTest <i>Strep A</i>	T820201PC T720201PC	15.70.01.03.00	13/07/2005 ES/CA01/02/235070-1
CerTest <i>RSV</i>	RV820001PC RV720001PC	15.70.90.02.00	02/02/2007 ES/CA01/02/38059-3
CerTest <i>Adenovirus Resp.</i>	AP820001PC AP720001PC	15.04.80.01.00	26/07/2007 ES/CA01/02/261163-01
CerTest <i>RSV-Adenovirus Resp.</i>	VR882001PC VR720301PC	15.70.90.02.00 & 15.04.80.01.00	26/07/2007 ES/CA01/02/261163-2
CerTest <i>Influenza A</i>	Y820001PC Y720001PC	15.04.80.04.00	17/11/2005 ES/CA01/02/370037-12
CerTest <i>Influenza A+B</i>	Z882001PC ZR720301PC	15.04.80.04.00	13/07/2005 ES/CA01/02/235070-2
CerTest <i>Influenza A+B+RSV</i>	ZS872001PC	15.70.90.04.00 & 15.70.90.02.00	15/12/2016 RPS/637/2016
CerTest <i>Influenza A+B+RSV+Adeno Resp.</i>	ZV862001P	15.04.08.04.00 & 15.70.90.02.00, 15.04.80.01.00	23/05/2012 RPS/512/2012
CerTest <i>Legionella</i>	LP820201PC	15.70.01.90.00	12/12/2008 ES/CA01/02/4240903
CerTest <i>Streptococcus pneumoniae</i>	SN820201PC	15.70.01.09.00	10/11/2016 RPS/600/2016
CerTest <i>S. pneumoniae</i> + <i>Legionella</i>	NL882201PC	15.70.01.09.00 & 15.70.01.08.00	22/12/2016 RPS/647/2016



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Product Name	REF	EDMS Code	Registration Date and Number
CerTest FOB Positive Control	F220001P	12.50.01.10.00	12/12/2008 ES/CA01/02/424092-4
CerTest Transferrin Positive Control	TF220001P	12.50.01.06.00	12/12/2008 ES/CA01/02/424092-15
CerTest Calprotectin Positive Control	CP220001P	15.50.01.06.00	07/09/2010 ES/CA01/02/326990-5
CerTest Lactoferrin Positive Control	LT220001P	12.50.01.06.00	12/12/2008 ES/CA01/02/424092-11
CerTest Rotavirus Positive Control	R220001P	15.50.01.04.00	12/12/2008 ES/CA01/02/424092-2
CerTest Adenovirus Positive Control	AD220001P	15.50.01.04.00	12/12/2008 ES/CA01/02/424092-1
CerTest Astrovirus Positive Control	AT220001P	15.50.01.04.00	28/04/2009 ES/CA01/02/1788003-8
CerTest Norovirus GI Positive Control	NG220001P	15.50.01.04.00	24/09/2013 RPS/873/2013
CerTest Norovirus GII Positive Control	NP220001P	15.50.01.04.00	24/09/2013 RPS/873/2013
CerTest Enterovirus Positive Control	EV220001P	15.50.01.04.00	29/03/2010 Registration number has been requested from Spanish Agency of Medical Products and Medical Devices (AEMPS)
CerTest Enterovirus 71 Positive Control	EN220001P	15.50.01.04.00	15/12/2016 RPS/637/2016
CerTest HAV Positive Control	HA220001P	15.50.01.02.00	12/12/2008 ES/CA01/02/424092-10
CerTest H. pylori Positive Control	P220001P	15.50.01.01.00	12/12/2008 ES/CA01/02/424092-7
CerTest C. difficile antigen GDH Positive Control	GD220001P	15.50.01.04.00	07/02/2012 RPS/114/2012
CerTest C. difficile Toxin A Positive Control	TA220001P	15.50.01.04.00	07/02/2012 RPS/114/2012
CerTest C. difficile Toxin B Positive Control	TB220001P	15.50.01.04.00	07/02/2012 RPS/114/2012
CerTest E. coli O157 Positive Control	E220001P	15.50.01.01.00	12/12/2008 ES/CA01/02/424092-13
CerTest EHEC VT1 Positive Control	VT220001P	15.50.01.01.00	24/09/2013 RPS/873/2013
CerTest EHEC VT2 Positive Control	VX220001P	15.50.01.01.00	24/09/2013 RPS/873/2013
CerTest Campylobacter Positive Control	CA220001P	15.50.01.01.00	24/11/2009 ES/CA01/02/464691-4
CerTest Salmonella Positive Control	SA220001P	15.50.01.01.00	24/11/2009 ES/CA01/02/464691-5
CerTest Salmonella typhi Positive Control	ST220001P	15.50.01.01.00	07/09/2010 ES/02/326990-4
CerTest Salmonella paratyphi Positive Control	SP220001P	15.50.01.04.00	20/03/2012 RPS/227/2012
CerTest Listeria Positive Control	LM220001P	15.50.01.01.00	24/11/2009 ES/CA01/02/464691-6
CerTest Shigella Positive Control	SH220001P	15.50.01.01.00	25/11/2010 ES/CA01/02/4232681-4
CerTest Shigella dysenteriae Positive Control	SD220001P	15.50.01.01.00	25/11/2010 ES/02/4232681-4
CerTest Shiga Toxin Positive Control	DT220001P	15.50.01.01.00	21/03/2014 RPS/87/2014
CerTest Yersinia enterocolitica O:3 Positive Control	YE220001P	15.50.01.01.00	24/09/2013 RPS/873/2013
CerTest Yersinia enterocolitica O:9 Positive Control	YC220001P	15.50.01.01.00	24/09/2013 RPS/873/2013
CerTest Crypto Positive Control	K220001P	15.50.01.05.00	12/12/2008 ES/CA01/02/424092-14



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Product Name	REF	EDMS Code	Registration Date and Number
CerTest Giardia Positive Control	G220001P	15.50.01.05.00	28/04/2009 ES/CA01/02/178803-11
CerTest Entamoeba Positive Control	EH220001P	15.50.01.05.00	24/09/2013 RPS/873/2013
CerTest Strep A Positive Control	T220001P	15.50.01.01.00	12/12/2008 ES/CA01/02/424092-6
CerTest RSV Positive Control	RV220001P	15.50.01.04.00	12/12/2008 ES/CA01/02/424092-5
CerTest Adenovirus Resp. Positive Control	AP220001P	15.50.01.04.00	24/04/2009 ES/CA01/02/178803-10
CerTest Influenza A Positive Control	Y220001P	15.50.01.04.00	28/04/2009 ES/CA01/02/1788003-7
CerTest Influenza B Positive Control	YB220001P	15.50.01.04.00	24/09/2013 RPS/873/2013
CerTest Influenza A+B Positive Control	ZR220001P	15.50.01.04.00	12/12/2008 ES/CA01/02/424092-3
CerTest Legionella Positive Control	LP220001P	15.50.01.01.00	12/12/2008 ES/CA01/02/424092-8
CerTest S. pneumoniae Positive Control	SN220001P	15.50.01.01.00	15/12/2016 RPS/637/2016
CerTest Negative Control	CN320001P	15.50.01.01.00	06/09/2012 RPS/685/2012

MANUFACTURER		
Name of company	Address	Representative
CERTEST BIOTEC S.L.	POL. INDUSTRIAL RIO GALLEG0 II, CALLE J, Nº 1, 50840, SAN MATEO DE GALLEG0, ZARAGOZA (SPAIN)	Oscar Landeta
CONFORMITY ASSESSMENT		
Device classification	Route of compliance	
Other IVD-Self declaration	Annex III of IVDD 98/79/EC Council Directive	

CerTest Biotec S.L. declares that the above mentioned products covered by this declaration conform with the Essential Requirements of EC Directive 98/79/EC (annex I).

Company representative. Oscar Landeta

Title: CEO. Signature:

Date January 30th, 2017