

EC DECLARATION OF CONFORMITY

IVD MEDICAL DEVICES DIRECTIVE 98/79/EC

MANUFACTURER:

CERTEST BIOTEC S.L.

ADDRESS:

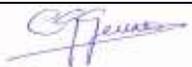
María de Luna 11, Nave 16
E-50018 Zaragoza (SPAIN)

DECLARES under their responsibility that the products covered by this declaration conform with the Essential Requirements of EC directive 98/79/EC (annex I):

- **CerTest FOB** (EDMS Code:12.03.90.04.00)
- **CerTest FOB 50+200** (EDMS Code:12.70.03.90.00)
- **CerTest FOB-Transferrin** (EDMS Code:12.70.03.90.00 & 12.70.01.90.00)
- **CerTest Calprotectin** (EDMS Code:12.70.01.90.00)
- **CerTest Calprotectin 50+200** (EDMS Code:12.70.01.90.00)
- **CerTest Lactoferrin** (EDMS Code: 12.70.01.90.00)
- **CerTest Calprotectin-Lactoferrin** (EDMS Code: 12.70.01.90.00)
- **CerTest FOB-Transferrin + Calprotectin-Lactoferrin** (EDMS Code: 12.70.03.90.00 & 12.70.01.90.00)
- **CerTest Rotavirus** (EDMS Code: 15.04.80.06.00)
- **CerTest Adenovirus** (EDMS Code:15.04.80.01.00)
- **CerTest Rotavirus-Adenovirus** (EDMS Code:15.04.80.06.00 & 15.04.80.01.00)
- **CerTest Rota-Adeno + Astrovirus** (EDMS Code:15.04.08.06.00, 15.04.80.01.00 & 15.70.90.90.00)
- **CerTest Astrovirus** (EDMS Code: 15.70.90.90.00)
- **CerTest Enterovirus** (EDMS Code:15.70.90.90.00)
- **CerTest HAV** (EDMS Code:15.70.02.90.00)
- **CerTest *H. pylori*** (EDMS Code:12.70.01.02.00)
- **CerTest *H. pylori* +Transferrin** (EDMS Code:12.70.01.02.00 & 12.70.01.90.00)
- **CerTest *E. coli*** (EDMS Code:15.01.15.01.00)
- **CerTest *Campylobacter*** (EDMS Code:15.70.01.90.00)
- **CerTest *Salmonella*** (EDMS Code:15.70.01.90.00)
- **CerTest *Salmonella Typhi*** (EDMS Code: 15.70.01.90.00)
- **CerTest *Listeria*** (EDMS Code: 15.70.01.90.00)
- **CerTest *Shigella*** (EDMS Code: 15.70.01.90.00)
- **CerTest *Shigella dysenteriae*** (EDMS Code: 15.70.01.90.00)

- **CerTest *Crypto*** (EDMS Code: 15.05.10.07.00)
- **CerTest *Giardia*** (EDMS Code: 15.05.10.08.00)
- **CerTest *Crypto-Giardia*** (EDMS Code:15.05.10.07.00 & 15.05.10.08.00)
- **CerTest *Strep A*** (EDMS Code:15.70.01.03.00)
- **CerTest *RSV*** (EDMS Code: 15.70.90.02.00)
- **CerTest *Adeno Resp.*** (EDMS Code:15.04.80.01.00)
- **CerTest *RSV-Adeno Resp.*** (EDMS Code: 15.70.90.02.00 & 15.04.80.01.00)
- **CerTest *Influenza A*** (EDMS Code: 15.04.80.04.00)
- **CerTest *Influenza A+B*** (EDMS Code: 15.04.80.04.00)
- **CerTest *hCG s&u*** (EDMS Code: 12.05.02.05.00)
- **CerTest *FOB Positive Control*** (EDMS Code: 12.50.01.10.00)
- **CerTest *Transferrin Positive Control*** (EDMS Code: 12.50.01.06.00)
- **CerTest *Calprotectin Positive Control*** (EDMS Code: 15.50.01.06.00)
- **CerTest *Lactoferrin Positive Control*** (EDMS Code: 12.50.01.06.00)
- **CerTest *Rotavirus Positive Control*** (EDMS Code: 15.50.01.04.00)
- **CerTest *Adenovirus Positive Control*** (EDMS Code: 15.50.01.04.00)
- **CerTest *Astrovirus Positive Control*** (EDMS Code:15.50.01.04.00)
- **CerTest *Enterovirus Positive Control*** (EDMS Code: 15.50.01.04.00)
- **CerTest *HAV Positive Control*** (EDMS Code: 15.50.01.02.00)
- **CerTest *H. pylori Positive Control*** (EDMS Code: 15.50.01.01.00)
- **CerTest *E. coli Positive Control*** (EDMS Code: 15.50.01.01.00)
- **CerTest *Campylobacter Positive Control*** (EDMS Code: 15.50.01.01.00)
- **CerTest *Salmonella Positive Control*** (EDMS Code: 15.50.01.01.00)
- **CerTest *Listeria Positive Control*** (EDMS Code: 15.50.01.01.00)
- **CerTest *Shigella Positive Control*** (EDMS Code: 15.50.01.01.00)
- **CerTest *Crypto Positive Control*** (EDMS Code: 15.50.01.05.00)
- **CerTest *Giardia Positive Control*** (EDMS Code: 15.50.01.05.00)
- **CerTest *Strep A Positive Control*** (EDMS Code: 15.50.01.01.00)
- **CerTests *RSV Positive Control*** (EDMS Code: 15.50.01.04.00)
- **CerTest *Adenovirus Respiratory Positive Control*** (EDMS Code: 15.50.01.04.00)
- **CerTest *Influenza A Positive Control*** (EDMS Code: 15.50.01.04.00)
- **CerTests *Influenza A+B Positive Control*** (EDMS Code: 15.50.01.04.00)
- **CerTests *hCG Positive Control*** (EDMS Code: 12.50.01.04.00)

DATE: **March 20 , 2012**

Name	Carlos Genzor Asín
	
Function	Safety officer

Product Name (IVD Medical Device)	Catalogue Reference	EDMS CODE	Classification per IVDD 98/79/EC	Registration Date and Number
CerTest FOB blister test(40 test kit with stool vials)	F740001LF	12.03.90.04.00	General IVDD Annex III of 98/79/EC	30/08/2004 ES/CA01/02/269823
CerTest FOB blister test (40 test kit with stool vials+ PC)	F740001LFC	12.03.90.04.00	General IVDD Annex III of 98/79/EC	30/08/2004 ES/CA01/02/269823
CerTest FOB blister test (10 test kit with stool vials)	F740001LF	12.03.90.04.00	General IVDD Annex III of 98/79/EC	30/08/2004 ES/CA01/02/269823
CerTest FOB 50+200 combo Card (10 test kit with stool vials)	FB881001F	12.70.03.90.00	General IVDD Annex III of 98/79/EC	15/04/2011 RPS/287/2011
CerTest FOB 50+200 combo card (20 test kit with stool vials)	FB882001F	12.70.03.90.00	General IVDD Annex III of 98/79/EC	15/04/2011 RPS/287/2011
CerTest FOB-Transferrin blister test (40 test kit with stool vials)	FT740001AF	12.70.03.90.00 & 12.70.01.90.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/4240905
CerTest FOB-Transferrin blister test (40 test kit with stool vials + PC)	FT740001AFC	12.70.03.90.00 & 12.70.01.90.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/4240905
CerTest FOB-Transferrin blister test (10 test kit with stool vials)	FT710001AF	12.70.03.90.00 & 12.70.01.90.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/4240905
CerTest Calprotectin blister test (40 test kit with stool vials)	CP740001LF	12.70.01.90.00	General IVDD Annex III of 98/79/EC	07/09/2010 ES/CA01/02/326990-2
CerTest Calprotectin blister test (40 test kit with stool vials+PC)	CP740001LFC	12.70.01.90.00	General IVDD Annex III of 98/79/EC	07/09/2010 ES/CA01/02/326990-2
CerTest Calprotectin blister test (10 test kit with stool vials)	CP710001LF	12.70.01.90.00	General IVDD Annex III of 98/79/EC	07/09/2010 ES/CA01/02/326990-2

Product Name (IVD Medical Device)	Catalogue Reference	EDMS CODE	Classification per IVDD 98/79/EC	Registration Date and Number
CerTest Calprotectin 50+200 combo card (10 test kit with stool vials)	CC881001F	12.70.01.90.00	General IVDD Annex III of 98/79/EC	24/02/2011 RPS/284/2011
CerTest Calprotectin 50+200 combo card (20 test kit with stool vials)	CC882001F	12.70.01.90.00	General IVDD Annex III of 98/79/EC	24/02/2011 RPS/284/2011
CerTest Calprotectin 50+200 combo card (20 test kit with stool vials+PC)	CC882001FC	12.70.01.90.00	General IVDD Annex III of 98/79/EC	24/02/2011 RPS/284/2011
CerTest Lactoferrin blister test (40 test kit with stool vials)	LF740101AF	12.70.01.90.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/4240906
CerTest Lactoferrin blister test (40 test kit with stools vials + PC)	LF740101AFC	12.70.01.90.00	General IVDD Annex III of 98/79/EC	12/12/2011 ES/CA01/02/4240906
CerTest Lactoferrin blister test (10 test kit with stool vials)	LF710101AF	12.70.01.90.00	General IVDD Annex III of 98/79/EC	12/12/2011 ES/CA01/02/4240906
CerTest Calprotectin-Lactoferrin blister test (40 test kit with stool vials)	CL740001AF	12.70.01.90.00	General IVDD Annex III of 98/79/EC	07/09/2010 ES/CA01/02/326990-3
CerTest Calprotectin-Lactoferrin blister test (40 test kit with stool vials+PC)	CL740001AFC	12.70.01.90.00	General IVDD Annex III of 98/79/EC	07/09/2011 ES/CA01/02/326990-3
CerTest Calprotectin-Lactoferrin blister test (10 test kit with stool vials)	CL710001AF	12.70.01.90.00	General IVDD Annex III of 98/79/EC	07/09/2011 ES/CA01/02/326990-3

Product Name (IVD Medical Device)	Catalogue Reference	EDMS CODE	Classification per IVDD 98/79/EC	Registration Date and Number
CerTest FOB-Transferrin+Calprotectin combo card (10 test kit)	FC881001F	12.70.03.90.00 & 12.70.01.90.00	General IVDD Annex III of 98/79/EC	15/04/2011 RPS/287/2011
CerTest FOB-Transferrin +Calprotectin-Lactoferrin Combo Card (20 test kit)	FC882001F	12.70.03.90.00 & 12.70.01.90.00	General IVDD Annex III of 98/79/EC	15/04/2011 RPS/287/2011
CerTest Rotavirus blister test (40 test kit with stool vials)	R740001AV	15.04.80.06.00	General IVDD Annex III of 98/79/EC	17/02/2004 ES/CA01/02/49023-2
CerTest Rotavirus blister test (40 test kit with stool vials+PC)	R740001AVC	15.04.80.06.00	General IVDD Annex III of 98/79/EC	17/02/2004 ES/CA01/02/49023-2
CerTest Rotavirus blister test (10 test kit with stools vials)	R710001AV	15.04.80.06.00	General IVDD Annex III of 98/79/EC	17/02/2004 ES/CA01/02/49023-2
CerTest Rotavirus tube (50 test kit)	R950001A	15.04.80.06.00	General IVDD Annex III of 98/79/EC	17/02/2004 ES/CA01/02/49023-2
CerTest Adenovirus blister test (40 test kit with stool vials)	A740001LV	15.04.80.01.00	General IVDD Annex III of 98/79/EC	17/02/2004 ES/CA01/02/49023-3
CerTest Adenovirus blister test (40 test kit with stool vials+PC)	A740001LVC	15.04.80.01.00	General IVDD Annex III of 98/79/EC	17/02/2004 ES/CA01/02/49023-3
CerTest Adenovirus blister test (10 test kit with stool vials)	A710001LV	15.04.80.01.00	General IVDD Annex III of 98/79/EC	17/02/2004 ES/CA01/02/49023-3
CerTest Adenovirus tube (50 test kit)	A950001L	15.04.80.06.00	General IVDD Annex III of 98/79/EC	17/02/2004 ES/CA01/02/49023-3

Product Name (IVD Medical Device)	Catalogue Reference	EDMS CODE	Classification per IVDD 98/79/EC	Registration Date and Number
CerTest Rota-Adeno blister tes (40 test kit with stool vials)	X740001LV	15.04.80.06.00 & 15.04.80.01.00	General IVDD Annex III of 98/79/EC	17/02/2004 ES/CA01/02/49023-4
CerTest Rota-Adeno blister tes (40 test kit with stool vials+PC)	X740001LVC	15.04.80.06.00 & 15.04.80.01.00	General IVDD Annex III of 98/79/EC	17/02/2004 ES/CA01/02/49023-4
CerTest Rota-Adeno blister tes (10 test kit with stool vials)	X710001LV	15.04.80.06.00 & 15.04.80.01.00	General IVDD Annex III of 98/79/EC	17/02/2004 ES/CA01/02/49023-4
CerTest Rota-Adeno tube (50 test kit)	X950001L	15.04.80.06.00 & 15.04.80.01.00	General IVDD Annex III of 98/79/EC	17/02/2004 ES/CA01/02/49023-4
CerTest Rota-Adeno+Astrovirus combo card (20 test kit with stools vials)	RT882001V	15.04.08.06.00, 15.04.80.01.00 & 15.70.90.90.00	General IVDD Annex III of 98/79/EC	24/02/2011 RPS/284/2011
CerTest Rota-Adeno+Astrovirus combo card (20 test kit with stools vials+PC)	RT882001VC	15.04.08.06.00, 15.04.80.01.00 & 15.70.90.90.00	General IVDD Annex III of 98/79/EC	24/02/2011 RPS/284/2011
CerTest Astrovirus blister test (40 test kit with stools vials)	AT740001LV	15.70.90.90.00	General IVDD Annex III of 98/79/EC	02/02/2007 ES/CA01/02/38059-1
CerTest Astrovirus blister test (40 test kit with stools vials+PC)	AT740001LVC	15.70.90.90.00	General IVDD Annex III of 98/79/EC	02/02/2007 ES/CA01/02/38059-1
CerTest Astrovirus blister test (10 test kit with stools vials)	AT710001LV	15.70.90.90.00	General IVDD Annex III of 98/79/EC	02/02/2007 ES/CA01/02/38059-1

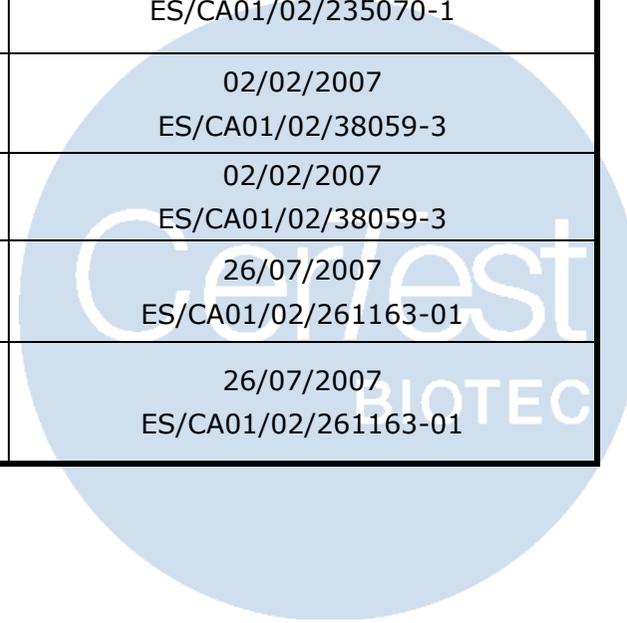
Product Name (IVD Medical Device)	Catalogue Reference	EDMS CODE	Classification per IVDD 98/79/EC	Registration Date and Number
CerTest Astrovirus tube (50 test kit)	AT950001L	15.70.90.90.00	General IVDD Annex III of 98/79/EC	02/02/2007 ES/CA01/02/38059-1
CerTest Enterovirus blister test (40 test kit with stool vials)	EV740001AV	15.70.90.90.00	General IVDD Annex III of 98/79/EC	29/03/2010 ES/CA01/02/38059-4
CerTest Enterovirus blister test (40 test kit with stool vials+PC)	EV740001AVC	15.70.90.90.00	General IVDD Annex III of 98/79/EC	29/03/2010 ES/CA01/02/38059-4
CerTest Enterovirus tube (50 test kit)	EV950001A	15.70.90.90.00	General IVDD Annex III of 98/79/EC	29/03/2010 ES/CA01/02/38059-4
CerTest HAV blister test (40 test kit with stool vials)	HA740001LV	15.70.02.90.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/4240902
CerTest HAV blister test (40 test kit with stool vials+PC)	HA740001LVC	15.70.02.90.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/4240902
CerTest HAV tube (50 test kit)	HA950001L	15.70.02.90.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/4240902
CerTest <i>H. pylori</i> blister test (40 test kit with stools vials)	P740001AV	15.70.01.02.00	General IVDD Annex III of 98/79/EC	17/11/2005 ES/CA01/02/370037-13
CerTest <i>H. pylori</i> blister test (40 test kit with stools vials+PC)	P740001AVC	15.70.01.02.00	General IVDD Annex III of 98/79/EC	17/11/2005 ES/CA01/02/370037-13
CerTest <i>H. pylori</i> blister test (10 test kit with stools vials)	P710001AV	15.70.01.02.00	General IVDD Annex III of 98/79/EC	17/11/2005 ES/CA01/02/370037-13

Product Name (IVD Medical Device)	Catalogue Reference	EDMS CODE	Classification per IVDD 98/79/EC	Registration Date and Number
CerTest <i>H. pylori</i> tube (50 test kit)	P950001A	15.70.01.02.00	General IVDD Annex III of 98/79/EC	17/11/2005 ES/CA01/02/370037-13
CerTest <i>H. pylori</i> + <i>Transferrin</i> Combo Card (10 test kit with stool vials)	PT881001VF	15.70.01.02.00 & 12.70.01.90.00	General IVDD Annex III of 98/79/EC	24/02/2011 RPS/284/2011
CerTest <i>H. pylori</i> + <i>Transferrin</i> Combo Card (20 test kit with stool vials)	PT882001VF	15.70.01.02.00 & 12.70.01.90.00	General IVDD Annex III of 98/79/EC	24/02/2011 RPS/284/2011
CerTest <i>H. pylori</i> + <i>Transferrin</i> Combo Card (20 test kit with stool vials+PC)	PT882001VFC	15.70.01.02.00 & 12.70.01.90.00	General IVDD Annex III of 98/79/EC	24/02/2011 RPS/284/2011
CerTest <i>E. coli</i> blister test (40 test kit with stool vials)	E740001AV	15.01.15.01.00	General IVDD Annex III of 98/79/EC	17/11/2005 ES/CA01/02/370037-16
CerTest <i>E. coli</i> blister test (40 test kit with stool vials+PC)	E740001AVC	15.01.15.01.00	General IVDD Annex III of 98/79/EC	17/11/2005 ES/CA01/02/370037-16
CerTest <i>E. coli</i> tube (50 test kit)	E950001A	15.01.15.01.00	General IVDD Annex III of 98/79/EC	17/11/2005 ES/CA01/02/370037-16
CerTest <i>Campylobacter</i> blister test (40 test kit with stools vials)	CA740001LV	15.70.01.90.00	General IVDD Annex III of 98/79/EC	24/11/2009 ES/CA01/02/464691-1
CerTest <i>Campylobacter</i> blister test (40 test kit with stools vials+PC)	CA740001LVC	15.70.01.90.00	General IVDD Annex III of 98/79/EC	24/11/2009 ES/CA01/02/464691-1
CerTest <i>Campylobacter</i> tube (50 test kit)	CA950001L	15.70.01.90.00	General IVDD Annex III of 98/79/EC	24/11/2009 ES/CA01/02/464691-1
CerTest <i>Salmonella</i> blister (40 test kit with stool vials)	SA740001LV	15.70.01.90.00	General IVDD Annex III of 98/79/EC	24/11/2009 ES/CA01/02/464691-2

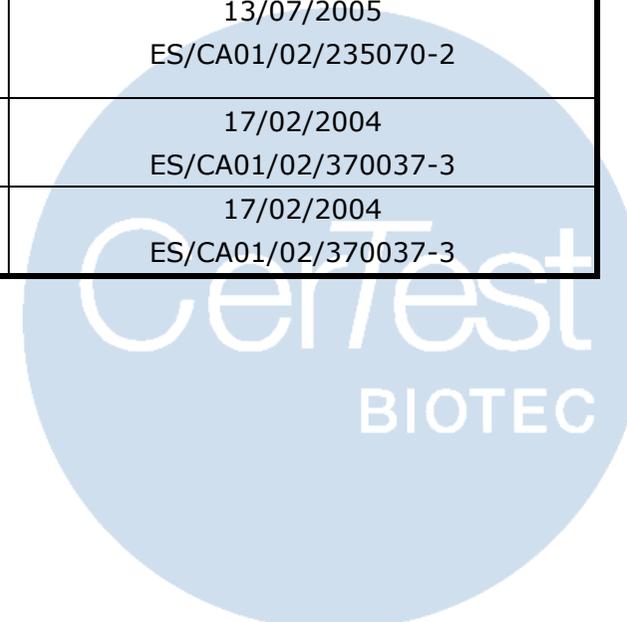
Product Name (IVD Medical Device)	Catalogue Reference	EDMS CODE	Classification per IVDD 98/79/EC	Registration Date and Number
CerTest <i>Salmonella</i> blister test(40 test kit with stool vials+PC)	SA740001LVC	15.70.01.09.00	General IVDD Annex III of 98/79/EC	24/11/2009 ES/CA01/02/464691-2
CerTest <i>Salmonella</i> tube (50 test kit)	SA950001L	15.70.01.09.00	General IVDD Annex III of 98/79/EC	24/11/2009 ES/CA01/02/464691-2
CerTest <i>Salmonella typhi</i> blister test (40 test kit with stool vials)	ST740001AV	15.70.01.90.00	General IVDD Annex III of 98/79/EC	07/09/2010 ES/CA01/02/326990-1
CerTest <i>Salmonella typhi</i> blister test (40 test kit with stool vials+PC)	ST740001AVC	15.70.01.90.00	General IVDD Annex III of 98/79/EC	07/09/2010 ES/CA01/02/326990-1
CerTest <i>Salmonella typhi</i> tube (50 test kit)	ST950001A	15.70.01.90.00	General IVDD Annex III of 98/79/EC	07/09/2010 ES/CA01/02/326990-1
CerTest <i>Listeria</i> blister test (40 test kit with stool vials)	LM740001AV	15.70.01.90.00	General IVDD Annex III of 98/79/EC	24/11/2009 ES/CA01/02/464691-3
CerTest <i>Listeria</i> blister test (40 test kit with stool vials+PC)	LM740001AVC	15.70.01.90.00	General IVDD Annex III of 98/79/EC	24/11/2009 ES/CA01/02/464691-3
CerTest <i>Listeria</i> tube (50 test kit)	LM950001A	15.70.01.90.00	General IVDD Annex III of 98/79/EC	24/11/2009 ES/CA01/02/464691-3
CerTest <i>Shigella</i> blister test (40 test kit with stool vials)	SH740001LV	15.70.01.90.00	General IVDD Annex III of 98/79/EC	25/11/2010 ES/CA01/02/422681-1
CerTest <i>Shigella</i> blister test (40 test kit with stool vials+PC)	SH740001LVC	15.70.01.90.00	General IVDD Annex III of 98/79/EC	25/11/2010 ES/CA01/02/422681-1

Product Name (IVD Medical Device)	Catalogue Reference	EDMS CODE	Classification per IVDD 98/79/EC	Registration Date and Number
CerTest <i>Shigella</i> tube (50 test kit)	SH950001L	15.70.01.90.00	General IVDD Annex III of 98/79/EC	25/11/2010 ES/CA01/02/422681-1
CerTest <i>Shigella dysenteriae</i> blister test(40 test kit with stool vials)	SD740001AV	15.70.01.90.00	General IVDD Annex III of 98/79/EC	25/11/2010 ES/CA01/02/422681-2
CerTest <i>Shigella dysenteriae</i> blister test(40 test kit with stool vials+PC)	SD740001AVC	15.70.01.90.00	General IVDD Annex III of 98/79/EC	25/11/2010 ES/CA01/02/422681-2
CerTest <i>Shigella dysenteriae</i> tube (50 test kit)	SD950001A	15.70.01.90.00	General IVDD Annex III of 98/79/EC	25/11/2010 ES/CA01/02/422681-2
CerTest <i>Crypto</i> blister test (40 test kit with stool vials)	K740001LV	15.05.10.07.00	General IVDD Annex III of 98/79/EC	04/06/2004 ES/CA01/02/179864-2
CerTest <i>Crypto</i> blister test (40 test kit with stool vials+PC)	K740001LVC	15.05.10.07.00	General IVDD Annex III of 98/79/EC	04/06/2004 ES/CA01/02/179864-2
CerTest <i>Crypto</i> tube (50 test kit)	K950001L	15.05.10.07.00	General IVDD Annex III of 98/79/EC	04/06/2004 ES/CA01/02/179864-2
CerTest <i>Giardia</i> blister test (40 test kit with stools vials)	G740001AV	15.05.10.08.00	General IVDD Annex III of 98/79/EC	17/11/2005 ES/CA01/02/370037-14
CerTest <i>Giardia</i> blister test (40 test kit with stool vials+PC)	G740001AVC	15.05.10.08.00	General IVDD Annex III of 98/79/EC	17/11/2005 ES/CA01/02/370037-14

Product Name (IVD Medical Device)	Catalogue Reference	EDMS CODE	Classification per IVDD 98/79/EC	Registration Date and Number
CerTest <i>Giardia</i> tube (50 test kit)	G950001A	15.05.10.08.00	General IVDD Annex III of 98/79/EC	17/11/2005 ES/CA01/02/370037-14
CerTest <i>Crypto-Giardia</i> blister test(40 test kit with stool vials)	N740001AV	15.05.10.07.00 & 15.05.10.08.00	General IVDD Annex III of 98/79/EC	17/11/2005 ES/CA01/02/370037-15
CerTest <i>Crypto-Giardia</i> blister test(40 test kit with stool vials+PC)	N740001AVC	15.05.10.07.00 & 15.05.10.08.00	General IVDD Annex III of 98/79/EC	17/11/2005 ES/CA01/02/370037-15
CerTest <i>Crypto-Giardia</i> tube (50 test kit)	N950001A	15.05.10.07.00 & 15.05.10.08.00	General IVDD Annex III of 98/79/EC	17/11/2005 ES/CA01/02/370037-15
CerTest Strep A blister test (20 test kit with swabs)	T720201APC	15.70.01.03.00	General IVDD Annex III of 98/79/EC	13/07/2005 ES/CA01/02/235070-1
CerTest Strep A tube (40 test kit)	T940201A	15.70.01.03.00	General IVDD Annex III of 98/79/EC	13/07/2005 ES/CA01/02/235070-1
CerTest RSV blister test (20 test kit with swabs)	RV720001APC	15.70.90.02.00	General IVDD Annex III of 98/79/EC	02/02/2007 ES/CA01/02/38059-3
CerTest RSV tube (50 test kit)	RV95001A	15.70.90.02.00	General IVDD Annex III of 98/79/EC	02/02/2007 ES/CA01/02/38059-3
CerTest <i>Adeno Resp.</i> blister test (20 test kit with swabs)	AN720001LPC	15.04.80.01.00	General IVDD Annex III of 98/79/EC	26/07/2007 ES/CA01/02/261163-01
CerTest <i>Adeno Resp.</i> tube (50 test kit)	AN950001L	15.04.80.01.00	General IVDD Annex III of 98/79/EC	26/07/2007 ES/CA01/02/261163-01



Product Name (IVD Medical Device)	Catalogue Reference	EDMS CODE	Classification per IVDD 98/79/EC	Registration Date and Number
CerTest <i>RSV-Adeno Resp.</i> blister test (20 test kit with swabs)	V720001APC	15.70.90.02.00 & 15.04.80.01.00	General IVDD Annex III of 98/79/EC	26/07/2007 ES/CA01/02/261163-2
CerTest <i>RSV-Adeno Resp.</i> tube (50 test kit)	V950001A	15.70.90.02.00 & 15.04.80.01.00	General IVDD Annex III of 98/79/EC	26/07/2007 ES/CA01/02/261163-2
CerTest <i>Influenza A</i> blister test (20 test kit with swabs)	Y720001LPC	15.04.80.04.00	General IVDD Annex III of 98/79/EC	17/11/2005 ES/CA01/02/370037-12
CerTest <i>Influenza A</i> tube (50 test kit)	Y950001L	15.04.80.04.00	General IVDD Annex III of 98/79/EC	17/11/2005 ES/CA01/02/370037-12
CerTest <i>Influenza A+B</i> blister test (20 test kit with swabs)	Z720001APC	15.04.80.04.00	General IVDD Annex III of 98/79/EC	13/07/2005 ES/CA01/02/235070-2
CerTest <i>Influenza A+B</i> tube (50 test kit)	Z950001A	15.04.80.04.00	General IVDD Annex III of 98/79/EC	13/07/2005 ES/CA01/02/235070-2
CerTest <i>hCG s&u</i> blister test (100 test kit)	SG700101A	12.05.02.05.00	General IVDD Annex III of 98/79/EC	17/02/2004 ES/CA01/02/370037-3
CerTest <i>hCG s&u</i> tube (100 test kit)	SG900101A	12.05.02.05.00	General IVDD Annex III of 98/79/EC	17/02/2004 ES/CA01/02/370037-3



Product Name (IVD Medical Device)	Catalogue Reference	EDMS CODE	Classification per IVDD 98/79/EC	Registration Date and Number
CerTest FOB Positive Control (20 controls per kit)	F220001P	12.50.01.10.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/424092-4
CerTest Transferrin Positive Control (20 controls per kit)	TF220001P	12.50.01.06.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/424092-15
CerTest Calprotectin Positive Control (20 controls per kit)	CP220001P	12.50.01.06.00	General IVDD Annex III of 98/79/EC	07/09/2010 ES/CA01/02/326990-5
CerTest Lactoferrin Positive Control (20 controls per kit)	LF220001P	15.50.01.06.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/424092-11
CerTest Rotavirus Positive Control (20 controls per kit)	R220001P	15.50.01.04.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/424092-2
CerTest Adenovirus Positive Control (20 controls per kit)	A220001P	15.50.01.04.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/424092-1
CerTest Astrovirus Positive Control (20 controls per kit)	AT220001P	15.50.01.04.00	General IVDD Annex III of 98/79/EC	28/04/2009 ES/CA01/02/1788003-8
CerTest Enterovirus Positive Control (20 controls per kit)	EV220001P	15.50.01.04.00	General IVDD Annex III of 98/79/EC	29/03/2010 Registration number has been requested from Spanish Agency of Medical Products and Medical Devices (AEMPS)
CerTest HAV Positive Control (20 controls per kit)	HA220001P	15.50.01.02.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/424092-10
CerTest <i>H. pylori</i> Positive Control (20 controls per kit)	P220001P	15.50.01.01.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/424092-7
CerTest <i>E. coli</i> Positive Control (20 controls per kit)	E220001P	15.50.01.01.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/424092-13
CerTest <i>Campylobacter</i> Positive Control (20 controls per kit)	CA220001P	15.50.01.01.00	General IVDD Annex III of 98/79/EC	24/11/2009 ES/CA01/02/464691-4

Product Name (IVD Medical Device)	Catalogue Reference	EDMS CODE	Classification per IVDD 98/79/EC	Registration Date and Number
CerTest <i>Salmonella</i> Positive Control (20 controls per kit)	SA220001P	15.50.01.01.00	General IVDD Annex III of 98/79/EC	24/11/2009 ES/CA01/02/464691-5
CerTest <i>Listeria</i> Positive Control (20 controls per kit)	LM220001P	15.50.01.01.00	General IVDD Annex III of 98/79/EC	07/09/2010 ES/CA01/02/464691-6
CerTest <i>Shigella</i> Positive Control (20 controls per kit)	SH220001P	15.50.01.01.00	General IVDD Annex III of 98/79/EC	25/11/2010 ES/CA01/02/4232681-4
CerTest <i>Crypto</i> Positive Control (20 controls per kit)	K220001P	15.50.01.05.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/424092-14
CerTest <i>Giardia</i> Positive Control (20 controls per kit)	G220001P	15.50.01.01.00	General IVDD Annex III of 98/79/EC	24/08/2009 ES/CA01/02/178803-11
CerTest Strep A Positive Control (20 controls per kit)	T220001P	15.50.01.01.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/424092-6
CerTest RSV Positive Control (20 controls per kit)	RV220001P	15.50.01.04.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/424092-5
CerTest <i>Adenovirus Respiratory</i> Positive Control (20 controls per kit)	AN220001P	15.50.01.04.00	General IVDD Annex III of 98/79/EC	24/04/2009 ES/CA01/02/178803-10
CerTest <i>Influenza A</i> Positive Control (20 controls per kit)	Y220001P	15.50.01.04.00	General IVDD Annex III of 98/79/EC	28/04/2009 ES/CA01/02/1788003-7
CerTest <i>Influenza A+B</i> Positive Control (20 controls per kit)	Z220001P	15.50.01.04.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/424092-3
CerTest hCG Positive Control (20 controls per kit)	SG220001P	12.50.01.04.00	General IVDD Annex III of 98/79/EC	12/12/2008 ES/CA01/02/424092-12

