

ACEMEDICAL

EC DECLARATION OF CONFORMITY

DOC. No: DOC20221221-01

Manufacturer: 33, Naeyoo-Road 124, Deogyang-gu, Goyang-si, Gyeonggi-do, Korea
Tel) 82-31-960-9200 Fax) 82-31-969-0527



EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Tel: (31) (0) 70 345-8570, Fax: (31) (0) 70 346-7299

Product : AutoFuser, AutoSelector

Classification : Class IIb (Rule 11, III CLASSIFICATION, Annex IX of MDD 93/42/EEC as amended by 2007/47/EC)

Applied Standard : EN ISO 13485, EN ISO 14971, EN ISO 10993-1, ISO 11135-1,
ISO 14644-1, ISO 15223-1, MEDDEV 2.7.1, NB-Med/2.7/REC.1

We here with declare that the above-mentioned products meet the provisions of the following EC Council Directives. All supporting documents are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives: Annex II (Excluding section 4) of Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC) as amended by Directive 2007/47 /EC.

CE Certificate number : KR19/81826293.00

Notified Body : SGS Belgium NV
SGS House, Noorderlaan 87 - 2030 Antwerpen

Signature

A handwritten signature in black ink, appearing to read 'Jong Woo Lee', is written over a horizontal line.

Name : Jong Woo Lee

Position : CEO

Date, Place : 2022-12-21

ACE MEDICAL Co., Ltd.



EC DECLARATION OF CONFORMITY

REF codes for following models in AutoFuser and AutoSelector are covered by this EC DOC.

- AutoFuser Continuous

No.	Product	Specification		REF Code
		Volume(mL)	Flow Rate(mL/hr)	
1	AutoFuser Continuous	100	0.59	AA1907
2			1.0	AA1901
3			2.0	AA1902
4			4.0	AA1904
5		150	0.9	AA1509
6			1.5	AA1511
7			3.0	AA1503
8			6.0	AA1506
9		275	1.5	AA2003
10			2.0	AA2002
11			5.0	AA2005
12	AutoFuser Continuous (Tubing Control)	100	0.59	AA1907-TC
13			1.0	AA1901-TC
14			2.0	AA1902-TC
15			4.0	AA1904-TC
16		150	0.9	AA1509-TC
17			1.5	AA1511-TC
18			3.0	AA1503-TC
19			6.0	AA1506-TC
20		275	1.5	AA2003-TC
21			2.0	AA2002-TC
22			5.0	AA2005-TC

- **AutoFuser Continuous possessing UV-Blocking functions**

No.	Product	Specification		REF Code
		Volume(mL)	Flow Rate(mL/hr)	
1	UV AutoFuser Continuous	100	0.59	UVAA1907
2			1.0	UVAA1901
3			2.0	UVAA1902
4			4.0	UVAA1904
5		150	0.9	UVAA1509
6			1.5	UVAA1511
7			3.0	UVAA1503
8			6.0	UVAA1506
9		275	1.5	UVAA2003
10			2.0	UVAA2002
11			5.0	UVAA2005
12	UV AutoFuser Continuous (Tubing Control)	100	0.59	UVAA1907-TC
13			1.0	UVAA1901-TC
14			2.0	UVAA1902-TC
15			4.0	UVAA1904-TC
16		150	0.9	UVAA1509-TC
17			1.5	UVAA1511-TC
18			3.0	UVAA1503-TC
19			6.0	UVAA1506-TC
20		275	1.5	UVAA2003-TC
21			2.0	UVAA2002-TC
22			5.0	UVAA2005-TC

- **AutoSelector Continuous**

No.	Product	Specification		REF Code
		Volume(mL)	Flow Rate(mL/hr)	
1	AutoSelector Continuous	100	A type	AFSC-A
2			B type	AFSC-A
3		275	A type	AFMC-A
4			B type	AFMC-B
5		550	A type	AFLC-A
6			B type	AFLC-B

- AutoSelector C&B PCM III type

No.	Product	Specification				REF Code	
		Volume (mL)	Flow Rate (mL/hr)	Bolus Dose (mL)	Refill Time (min)		
1	AutoSelector C&B PCM III type	100	A type	0.5	10	AFSP-0.5AA	
2					15	AFSP-0.5BA	
3					30	AFSP-0.5CA	
4					60	AFSP-0.5DA	
5				1.0	10	AFSP-1AA	
6					15	AFSP-1BA	
7					30	AFSP-1CA	
8					60	AFSP-1DA	
9				2.0	10	AFSP-2AA	
10					15	AFSP-2BA	
11					30	AFSP-2CA	
12					60	AFSP-2DA	
13				3.0	10	AFSP-3AA	
14					15	AFSP-3BA	
15					30	AFSP-3CA	
16					60	AFSP-3DA	
17				5.0	10	AFSP-5AA	
18					15	AFSP-5BA	
19					30	AFSP-5CA	
20					60	AFSP-5DA	
21				B type	0.5	10	AFSP-0.5AB
22						15	AFSP-0.5BB
23						30	AFSP-0.5CB
24						60	AFSP-0.5DB
25					1.0	10	AFSP-1AB
26						15	AFSP-1BB
27						30	AFSP-1CB
28						60	AFSP-1DB
29					2.0	10	AFSP-2AB
30						15	AFSP-2BB
31						30	AFSP-2CB
32						60	AFSP-2DB
33				3.0	10	AFSP-3AB	
34					15	AFSP-3BB	
35					30	AFSP-3CB	
36					60	AFSP-3DB	

37				5.0	10	AFSP-5AB
38			15		AFSP-5BB	
39			30		AFSP-5CB	
40			60		AFSP-5DB	

No.	Product	Specification				REF Code	
		Volume (mL)	Flow Rate (mL/hr)	Bolus Dose (mL)	Refill Time (min)		
1	AutoSelector C&B PCM III type	275	A type	0.5	10	AFMP-0.5AA	
2					15	AFMP-0.5BA	
3					30	AFMP-0.5CA	
4					60	AFMP-0.5DA	
5				1.0	10	AFMP-1AA	
6					15	AFMP-1BA	
7					30	AFMP-1CA	
8					60	AFMP-1DA	
9				2.0	10	AFMP-2AA	
10					15	AFMP-2BA	
11					30	AFMP-2CA	
12					60	AFMP-2DA	
13				3.0	10	AFMP-3AA	
14					15	AFMP-3BA	
15					30	AFMP-3CA	
16					60	AFMP-3DA	
17				5.0	10	AFMP-5AA	
18					15	AFMP-5BA	
19					30	AFMP-5CA	
20					60	AFMP-5DA	
21				B type	0.5	10	AFMP-0.5AB
22						15	AFMP-0.5BB
23						30	AFMP-0.5CB
24						60	AFMP-0.5DB
25					1.0	10	AFMP-1AB
26						15	AFMP-1BB
27						30	AFMP-1CB
28						60	AFMP-1DB
29				2.0	10	AFMP-2AB	
30					15	AFMP-2BB	
31					30	AFMP-2CB	
32					60	AFMP-2DB	

33				3.0	10	AFMP-3AB
34			15		AFMP-3BB	
35			30		AFMP-3CB	
36			60		AFMP-3DB	
37			5.0	10	AFMP-5AB	
38				15	AFMP-5BB	
39				30	AFMP-5CB	
40				60	AFMP-5DB	

No.	Product	Specification				REF Code	
		Volume (mL)	Flow Rate (mL/hr)	Bolus Dose (mL)	Refill Time (min)		
1	AutoSelector C&B PCM III type	550	A type	0.5	10	AFLP-0.5AA	
2					15	AFLP-0.5BA	
3					30	AFLP-0.5CA	
4					60	AFLP-0.5DA	
5				1.0	10	AFLP-1AA	
6					15	AFLP-1BA	
7					30	AFLP-1CA	
8					60	AFLP-1DA	
9				2.0	10	AFLP-2AA	
10					15	AFLP-2BA	
11					30	AFLP-2CA	
12					60	AFLP-2DA	
13				3.0	10	AFLP-3AA	
14					15	AFLP-3BA	
15					30	AFLP-3CA	
16					60	AFLP-3DA	
17				5.0	10	AFLP-5AA	
18					15	AFLP-5BA	
19					30	AFLP-5CA	
20					60	AFLP-5DA	
21				B type	0.5	10	AFLP-0.5AB
22						15	AFLP-0.5BB
23						30	AFLP-0.5CB
24						60	AFLP-0.5DB
25				1.0	10	AFLP-1AB	
26					15	AFLP-1BB	
27					30	AFLP-1CB	

28					60	AFLP-1DB
29				2.0	10	AFLP-2AB
30			15		AFLP-2BB	
31			30		AFLP-2CB	
32			60		AFLP-2DB	
33			3.0		10	AFLP-3AB
34				15	AFLP-3BB	
35				30	AFLP-3CB	
36				60	AFLP-3DB	
37			5.0	10	AFLP-5AB	
38				15	AFLP-5BB	
39				30	AFLP-5CB	
40				60	AFLP-5DB	

- **AutoSelector Continuous possessing UV-Blocking functions**

No.	Product	Specification		REF Code
		Volume(mL)	Flow Rate(mL/hr)	
1	UV AutoSelector Continuous	100	A type	UFSC-A
2			B type	UFSC-A
3		275	A type	UFMC-A
4			B type	UFMC-B
5		550	A type	UFCL-A
6			B type	UFCL-B

- AutoSelector C&B PCM III type possessing UV-Blocking functions

No.	Product	Specification				REF Code	
		Volume (mL)	Flow Rate (mL/hr)	Bolus Dose (mL)	Refill Time (min)		
1	UV AutoSelector C&B PCM III type	100	A type	0.5	10	2USSP-0.5AA	
2					15	2USSP-0.5BA	
3					30	2USSP-0.5CA	
4					60	2USSP-0.5DA	
5				1.0	10	2USSP-1AA	
6					15	2USSP-1BA	
7					30	2USSP-1CA	
8					60	2USSP-1DA	
9				2.0	10	2USSP-2AA	
10					15	2USSP-2BA	
11					30	2USSP-2CA	
12					60	2USSP-2DA	
13				3.0	10	2USSP-3AA	
14					15	2USSP-3BA	
15					30	2USSP-3CA	
16					60	2USSP-3DA	
17				5.0	10	2USSP-5AA	
18					15	2USSP-5BA	
19					30	2USSP-5CA	
20					60	2USSP-5DA	
21				B type	0.5	10	2USSP-0.5AB
22						15	2USSP-0.5BB
23						30	2USSP-0.5CB
24						60	2USSP-0.5DB
25					1.0	10	2USSP-1AB
26						15	2USSP-1BB
27						30	2USSP-1CB
28						60	2USSP-1DB
29					2.0	10	2USSP-2AB
30						15	2USSP-2BB
31						30	2USSP-2CB
32						60	2USSP-2DB
33				3.0	10	2USSP-3AB	
34					15	2USSP-3BB	
35					30	2USSP-3CB	
36					60	2USSP-3DB	

37				5.0	10	2USSP-5AB
38			15		2USSP-5BB	
39			30		2USSP-5CB	
40			60		2USSP-5DB	

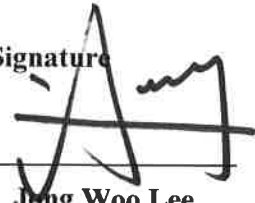
No.	Product	Specification				REF Code	
		Volume (mL)	Flow Rate (mL/hr)	Bolus Dose (mL)	Refill Time (min)		
1	UV AutoSelector C&B PCM III type	275	A type	0.5	10	2USMP-0.5AA	
2					15	2USMP-0.5BA	
3					30	2USMP-0.5CA	
4					60	2USMP-0.5DA	
5				1.0	10	2USMP-1AA	
6					15	2USMP-1BA	
7					30	2USMP-1CA	
8					60	2USMP-1DA	
9				2.0	10	2USMP-2AA	
10					15	2USMP-2BA	
11					30	2USMP-2CA	
12					60	2USMP-2DA	
13				3.0	10	2USMP-3AA	
14					15	2USMP-3BA	
15					30	2USMP-3CA	
16					60	2USMP-3DA	
17				5.0	10	2USMP-5AA	
18					15	2USMP-5BA	
19					30	2USMP-5CA	
20					60	2USMP-5DA	
21				B type	0.5	10	2USMP-0.5AB
22						15	2USMP-0.5BB
23						30	2USMP-0.5CB
24						60	2USMP-0.5DB
25					1.0	10	2USMP-1AB
26						15	2USMP-1BB
27						30	2USMP-1CB
28						60	2USMP-1DB
29				2.0	10	2USMP-2AB	
30					15	2USMP-2BB	
31					30	2USMP-2CB	
32					60	2USMP-2DB	

33				3.0	10	2USMP-3AB
34			15		2USMP-3BB	
35			30		2USMP-3CB	
36			60		2USMP-3DB	
37			5.0	10	2USMP-5AB	
38				15	2USMP-5BB	
39				30	2USMP-5CB	
40				60	2USMP-5DB	

No.	Product	Specification				REF Code	
		Volume (mL)	Flow Rate (mL/hr)	Bolus Dose (mL)	Refill Time (min)		
1	UV AutoSelector C&B PCM III type	550	A type	0.5	10	2USLP-0.5AA	
2					15	2USLP-0.5BA	
3					30	2USLP-0.5CA	
4					60	2USLP-0.5DA	
5				1.0	10	2USLP-1AA	
6					15	2USLP-1BA	
7					30	2USLP-1CA	
8					60	2USLP-1DA	
9				2.0	10	2USLP-2AA	
10					15	2USLP-2BA	
11					30	2USLP-2CA	
12					60	2USLP-2DA	
13				3.0	10	2USLP-3AA	
14					15	2USLP-3BA	
15					30	2USLP-3CA	
16					60	2USLP-3DA	
17				5.0	10	2USLP-5AA	
18					15	2USLP-5BA	
19					30	2USLP-5CA	
20					60	2USLP-5DA	
21				B type	0.5	10	2USLP-0.5AB
22						15	2USLP-0.5BB
23						30	2USLP-0.5CB
24						60	2USLP-0.5DB
25					1.0	10	2USLP-1AB
26						15	2USLP-1BB
27						30	2USLP-1CB
28						60	2USLP-1DB

29				2.0	10	2USLP-2AB
30			15		2USLP-2BB	
31			30		2USLP-2CB	
32			60		2USLP-2DB	
33			3.0	10	2USLP-3AB	
34				15	2USLP-3BB	
35				30	2USLP-3CB	
36				60	2USLP-3DB	
37			5.0	10	2USLP-5AB	
38				15	2USLP-5BB	
39				30	2USLP-5CB	
40				60	2USLP-5DB	

Signature



Name : Jong Woo Lee

Position : CEO

Date, Place : 2022-12-21

ACE MEDICAL Co., Ltd.