



## Declaration of Conformity

**Product:** Elastomeric Infusion Pumps and Systems

**Product Codes:** See attached product list

**UMDNS:** 16491 (Infusion Pumps, Ambulatory)

**GMDN:** 46542 (Elastomeric Infusion Pump Systems)  
47190 (Elastomeric Infusion pump kit)

**CE Manufacturer:** Kimberly-Clark  
1400 Holcomb Bridge Road  
Roswell, Georgia (GA) 30076  
USA

**EEC Representative:** Kimberly-Clark N. V.  
Da Vincilaan 1  
1935 Zaventem  
Belgium

**Product Standards:** ISO 28620:2010  
ISO 8536-4:2007

**Classification Rule(s):** IIb (as per Rule 11 of Annex IX)

**Start of CE:** See attached product list

**CE Certificate Number:** CE 614124

**Notified Body:** BSI (0086)

**ISO Certificate No.:** FM 572883 from BSI

We hereby declare that the above mentioned devices comply with the provisions of the European 93/42/EEC Council Directive on Medical Devices.

This declaration of conformity is issued under the sole responsibility of Kimberly-Clark and is valid for the products listed on the attached product list in their original, unmodified packaging.

A handwritten signature in blue ink that reads "Shelly Harris".

Shelly Harris  
I-Flow, LLC, A Kimberly-Clark Health Care Company  
Associate Director, Regulatory Affairs  
Issue Date: June 20, 2015



## Annex to the Declaration of Conformity (Product List)

### PRODUCT LIST Elastomeric Infusion Pumps and Systems

This product list belongs to the Declaration of Conformity identified by Elastomeric Infusion Pumps and Systems and specifies the CE marked products concerned that I-FLOW intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Ref No:	SAP Part Number	Description	Start of CE
C060020	101355702	Homepump C-Series, 60 ml, 2 ml/hr	May 1998
C100020	101356103	Homepump C-Series, 100 ml, 2 ml/hr	May 1998
C100020	101356200	Homepump C-Series, 100 ml, 2 ml/hr (Braun Korea)	May 1998
C125050	101356302	Homepump C-Series, 125 ml, 5 ml/hr	May 1998
C270020	101356602	Homepump C-Series, 270 ml, 2 ml/hr	May 1998
C270050	101356802	Homepump C-Series, 270 ml, 5 ml/hr	May 1998
C270100	101356902	Homepump C-Series, 270 ml, 10 ml/hr	May 1998
C300060	101357000	Homepump C-Series, 300 ml, 6 ml/hr	May 1998
E251750	101355200	Homepump Eclipse, 250 ml, 175 ml/hr	May 1998
E252500	101355300	Homepump Eclipse, 250 ml, 250 ml/hr	May 1998
E401000	101355400	Homepump Eclipse, 400 ml, 100 ml/hr	May 1998
E402000	101355500	Homepump Eclipse, 400 ml, 200 ml/hr	May 1998
E502500	101355600	Homepump Eclipse, 500 ml, 250 ml/hr	May 1998
SE050500	101357200	Homepump Eclipse, 50 ml, 50 ml/hr	May 1998
SE100500	101357300	Homepump Eclipse, 100 ml, 50 ml/hr	May 1998
SE101000	101357400	Homepump Eclipse, 100 ml, 100 ml/hr	May 1998
SE102000	101357500	Homepump Eclipse, 100 ml, 200 ml/hr	May 1998
04434350	101372600	ST 100-1, Easypump, 100 ml, 100 ml/hr	Sep 1998
04434352	101373300	ST 50-1, Easypump, 50 ml, 50 ml/hr	Sep 1998
04434354	101372500	ST 100-0.5, Easypump, 100 ml, 200 ml/hr	Sep 1998
04434356	101372700	ST 100-2, Easypump, 100 ml, 50 ml/hr	Sep 1998
04434358	101372800	ST 250-1.5, Easypump, 250 ml, 175 ml/hr	Sep 1998
04434360	101373100	ST 400-4, Easypump, 400 ml, 100 ml/hr	Sep 1998
04434362	101372900	ST 400-2, Easypump, 400 ml, 200 ml/hr	Sep 1998
04434364	101373200	ST 500-2, Easypump, 500 ml, 250 ml/hr	Sep 1998
04434366	101359600	LT 60-24, Easypump, 60 ml, 2 ml/hr	Sep 1998
04434368	101359000	LT 125-24, Easypump, 125 ml, 5 ml/hr	Sep 1998
04434370	101358700	LT 100-48, Easypump, 100 ml, 2 ml/hr	Sep 1998
04434372	101359800	LT 65-120, Easypump, 65 ml, 0.5 ml/hr	Sep 1998
04434374	101359400	LT 270-270, Easypump, 270 ml, 1 ml/hr	Sep 1998
04434376	101359200	LT 270-132, Easypump, 270 ml, 2 ml/hr	Sep 1998
04434378	101359300	LT 270-24, Easypump, 270 ml, 10 ml/hr	Sep 1998
04434380	101358600	LT 100-200, Easypump, 100 ml, 0.5 ml/hr	Sep 1998
04438043	101359500	LT 270-54, Easypump, 270 ml, 5 ml/hr	Sep 1998
PS12502	101360300	ON-Q Pain Relief System Intl, 12.5 Soaker Kit, 100 ml, 2 ml/hr	June 2006
PS12503	101360400	ON-Q Pain Relief System Intl, 12.5 Soaker Kit, 270 ml, 2 ml/hr	June 2006
PS12504	101364600	ON-Q Pain Relief System Soaker 12.5 Intl, 270 ml x 5 ml/hr	June 2006
PS12505	101360500	ON-Q Pain Relief System Intl, 12.5 Soaker Kit, 270 ml, Dual 2 ml/hr	June 2006
PS12506	101364700	ON-Q Pain Relief System Soaker 12.5 Intl, 400 ml x 5 ml/hr	June 2006
PS12507	101364800	ON-Q Pain Relief System Soaker 12.5 Intl, 400 ml x 10 ml/hr	June 2006



Ref No:	SAP Part Number	Description	Start of CE
PS12508	101364900	ON-Q Pain Relief System Soaker 12.5 Intl, 400 ml x Dual 2 ml/hr	June 2006
PS2501	101365300	ON-Q Pain Relief System Soaker 2.5 Intl, 100 ml, 1 ml/hr	June 2006
PS2502	101343300	ON-Q Pain Relief System Soaker 2.5 Intl, 100 ml, 2 ml/hr	June 2006
PS2504	101343400	ON-Q Pain Relief System Soaker 2.5 Intl, 270 ml, 5 ml/hr	June 2006
PS25005	101365000	ON-Q Pain Relief System Soaker 25 cm (10 in) Intl, 270 ml x Dual 2 ml/hr	June 2006
PS25006	101365100	ON-Q Pain Relief System Soaker 25 cm (10 in) Intl, 400 ml x 5 ml/hr	June 2006
PS25008	101365200	ON-Q Pain Relief System Soaker 25 cm (10 in) Intl, 400 ml x Dual 2 ml/hr	June 2006
PS6502	101365400	ON-Q Pain Relief System Soaker 6.5 Intl, 100 ml x 2 ml/hr	June 2006
PS6503	101365500	ON-Q Pain Relief System Soaker 6.5 Intl, 270 ml x 2 ml/hr	June 2006
PS6504	101365600	ON-Q Pain Relief System Soaker 6.5 Intl, 270 ml x 5 ml/hr	June 2006
PS6505	101365700	ON-Q Pain Relief System Soaker 6.5 Intl, 270 ml x Dual 2 ml/hr	June 2006
PS6506	101365800	ON-Q Pain Relief System Soaker 6.5 Intl, 400 ml, 5 ml/hr	June 2006
PS6507	101365900	ON-Q Pain Relief System Soaker 6.5 Intl, 400 ml, 10 ml/hr	June 2006
PS6508	101366000	ON-Q Pain Relief System Soaker 6.5 Intl, 400 ml x Dual 2 ml/hr	June 2006
PS400X6T	101360600	ON-Q Pain Relief System Intl, 400 ml x Triple 2 ml/hr, Pump	Mar 2007
P400X6T	101367802	ON-Q Pain Relief System Intl, 400 ml x Triple 2 ml/hr, Pump	June 2015
PS100X2D	104419600	ON-Q Pain Relief System with Dual Sites, 100ml, 2 ml/hr	June 2015
PS100X2	104419700	ON-Q Pain Relief System Pump with Fixed Flow Rate, 100ml, 2 ml/hr	June 2015
PS270X2	104419800	ON-Q Pain Relief System with Fixed Flow Rate, 270ml, 2 ml/hr	June 2015
PS270X4D	104419900	ON-Q Pain Relief System with Dual Sites, 270ml, 4ml/hr	June 2015
PS270X4	104421300	ON-Q Pain Relief System with Fixed Flow Rate, 270ml, 4 ml/hr	June 2015
PS270X5	104421100	ON-Q Pain Relief System with Fixed Flow Rate, 270ml, 5 ml/hr	June 2015
PS400X4D	104421200	ON-Q Pain Relief System with Dual Sites, 400ml, 4 ml/hr	June 2015
PS400X4	104421400	ON-Q Pain Relief System with Fixed Flow Rate, 400ml, 4 ml/hr	June 2015
PS400X8	104408000	ON-Q Pain Relief System with Fixed Flow Rate, 400ml, 8 ml/hr	June 2015
04434348	101346600	04434348, CB 270-54 Easypump, 270 ml, 5 ml/hr	Jun 2007
CBI001	101347800	ON-Q C-bloc Intl, 400 ml x 5 ml/hr	Jan 2003
CBI002	101347900	ON-Q C-bloc Intl, 400 ml x 10 ml/hr	Jan 2003
CBI003	101348000	ON-Q C-bloc Intl w/ OnDemand, 400 ml x 5 ml/hr + 5 ml/60 min	Jan 2003
CBI004	101348100	ON-Q C-bloc Intl with Select-A-Flow, 400 ml x 2-14 ml/hr	Jan 2003
CBI005	101348200	ON-Q C-bloc Intl w/Select-A-Flow & OnDemand, 400 x 1-7 + 5 ml/60 min	Jan 2003
CBI006	101348300	ON-Q C-bloc Intl w/ Select-A-Flow & OnDemand, 400 x 2-14 ml/hr + 5 ml/30 min	Jan 2003
CBI6004	101348400	ON-Q C-bloc Intl w/ Dual Select-A-Flow, 600 ml x 1-7 ml/hr + 1-7 ml/hr	Jan 2003
CBI6007	101348500	ON-Q C-bloc Intl w/ Dual Select-A-Flow, 600 ml x 1-7 ml/hr + 1-7 ml/hr	Jan 2003
PSAF01	101360900	ON-Q Pain Relief System Intl Kit, 270 ml x 1-7 ml/hr	Dec 2005
PSAF02	101366100	ON-Q Pain Relief System w/ SAF and Soaker Catheter, 6.5 Intl, 270 ml x 1-7 ml/hr	Dec 2005
4440003	101352800	RA 400-5, Easypump C-bloc, 400 ml, 5 ml/hr	Sep 1998
4440004	101352900	RA 400-8, Easypump C-bloc, 400 ml, 8 ml/hr	Sep 1998
4440005	101353000	RA 400-10, Easypump C-bloc, 400 ml, 10 ml/hr	Sep 1998
4440006	101348600	RA 400-5 PCA, Easypump C-bloc, 400 x 5 + 5 ml/60 min	Sep 1998
4440007	101348700	RA SAF 2-14, Easypump C-bloc with Select-A-Flow, 400 x 2-14	Sep 1998
4440008	101353100	RA PCA & SAF 2-14, Easypump C-bloc SAF/PCA, 400 x 2-14 + 5 ml/30 min	Sep 1998
4440009	101348800	RA SAF 1-7, Easypump C-bloc with Select-A-Flow, 270 x 1-7	Sep 1998
C060020	101355701	Homepump C-Series, 60 ml, 2 ml/hr, Non DEHP	Feb 2012
C100005	101356001	Homepump C-Series, 100 ml, 0.5 ml/hr, Non DEHP	Feb 2012
C100020	101356101	Homepump C-Series, 100 ml, 2 ml/hr, Non DEHP	Feb 2012
C125050	101356301	Homepump C-Series, 125 ml, 5 ml/hr, Non DEHP	Feb 2012
PS12502	101360301	ON-Q Pain Relief System Intl, 12.5 Soaker Kit, 100 ml, 2 ml/hr, Non DEHP	Feb 2012
PS2501	101365301	ON-Q Pain Relief System Soaker 2.5 Intl, 100 ml, 1 ml/hr, Non DEHP	Feb 2012
PS2502	101343301	ON-Q Pain Relief System Soaker 2.5 Intl, 100 ml, 2 ml/hr, Non DEHP	Feb 2012
PS6502	101365401	ON-Q Pain Relief System Soaker 6.5 Intl, 100 ml x 2 ml/hr, Non DEHP	Feb 2012
SE050500	101357201	Homepump Eclipse, 50 ml, 50 ml/hr, Non DEHP	Feb 2012
SE100500	101357301	Homepump Eclipse, 100 ml, 50 ml/hr, Non DEHP	Feb 2012



SE101000	101357401	Homepump Eclipse, 100 ml, 100 ml/hr, Non DEHP	Feb 2012
SE102000	101357501	Homepump Eclipse, 100 ml, 200 ml/hr, Non DEHP	Feb 2012